

**Concise Explanatory Statement  
(RCW 34.05.325.6a)**

**WAC 296-307-148, Cholinesterase Monitoring**

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# Concise Explanatory Statement (RCW 34.05.325.6a)

## WAC 296-307-148, Cholinesterase Monitoring

### EXECUTIVE SUMMARY

*This document has been prepared in compliance with section 34.05.325 of the Administrative Procedure Act (APA). Included are the reasons for adopting the rule, a description of the proposed rule and the text of the rule as adopted, and a summary of all comments received and responses to comments by category.*

Organophosphate and N-methyl carbamate pesticides are highly toxic and present a significant risk to agricultural pesticide handlers. The toxic symptoms accompanying exposure to organophosphate and N-methyl carbamate pesticides are associated with the inhibition of the enzyme acetylcholinesterase (AChE) in the nervous system. Inhibition of AChE causes cholinesterase depression that can result in cholinergic poisoning. The clinical symptoms of cholinergic poisoning are most notable in relation to over stimulation of the autonomic nervous system pathways. These include, but are not limited to, pupil dilation, nausea, diarrhea, and excess sweating, salivation and urination. Severe cases of poisoning can result in muscle twitching, changes in heart rate, convulsions, difficulty breathing and death. Research has indicated that there may be an association between exposure to cholinesterase inhibiting pesticides and long-term adverse effects such as changes in personality and memory loss.

The Environmental Protection Agency (EPA) has determined that cholinesterase inhibition in the blood is an appropriate surrogate measurement of cholinesterase activity in the peripheral and central nervous systems. The EPA states "Blood cholinesterase inhibition (RBC and/or plasma) is considered as providing a sufficient basis for removing workers from the exposure environment, given the assumption that if one were to protect against enzyme inhibition, one would protect against the effects of graver concern.<sup>1</sup> The World Health Organization (WHO)<sup>2</sup>, the American Conference of Governmental Industrial Hygienists (ACGIH)<sup>3</sup> and the National Institute of Occupational Safety and Health (NIOSH)<sup>4</sup> have all provided reference values for significant exposure to cholinesterase-inhibiting pesticides. The state of California has had a mandatory cholinesterase-monitoring rule in place since 1974.

The primary goal of the cholinesterase-monitoring program in this rule is to protect the health and safety of agricultural pesticide handlers by identifying cholinesterase

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<sup>1</sup> Environmental Protection Agency. The use of data on cholinesterase inhibition for risk assessments of organophosphorous and carbamate compounds. Office of Pesticide Programs. 2000. Washington DC.

<sup>2</sup> World Health Organization. Organophosphorous pesticides: A general introduction Environmental health Criteria 63.

<sup>3</sup> American Conference of Governmental Industrial Hygienists. Acetylcholinesterase inhibiting pesticides. 2001. TLVs and BEIs for 2001.

<sup>4</sup> U.S National Institute for Occupational Safety and Health. Criteria for a recommended standard: occupational exposure to parathion. 1976.

depression and taking actions to protect employees from further exposure that could lead to cholinergic poisoning. Additional benefits include, but are not limited to

- Increased worker awareness of the hazards of chemicals handled
- Identification and correction of unsafe work practices or conditions.
- Prevention of chronic effects of low-level exposures
- Aiding in clinical management of poisoned employees

Recognizing these benefits, L&I adopted a cholinesterase monitoring recommendation in 1993. In deciding not to adopt a mandatory monitoring rule at that time the department relied on the limitations that the EPA had identified in its decision not to include cholinesterase monitoring in the Pesticide worker Protection Standard, primarily limitations in available laboratory testing methodology and a lack of necessary infrastructure to support a large scale monitoring program.<sup>5</sup> This decision was supported in the 1995 Technical Advisory Group (TAG) Report on Cholinesterase Monitoring in Washington State. The TAG recognized the potential benefits of cholinesterase monitoring but stopped short of recommending the adoption of a mandatory cholinesterase-monitoring rule at that time.<sup>6</sup>

In 1997, L&I denied a request to make cholinesterase monitoring mandatory. After the Washington State Supreme Court ruled in *Rios et al v. Washington State Department of Labor & Industries et al*<sup>7</sup> that this decision was arbitrary and capricious, L&I initiated rulemaking on a mandatory cholinesterase-monitoring rule for agricultural pesticide handlers pursuant to the Washington State Supreme Court decision. Rulemaking activities have included:

- Formation of a stakeholder advisory group
- Conducting public data gathering meetings
- Conducting a telephone survey of growers
- Evaluating the best available evidence
- Filing a cholinesterase monitoring rule proposal
- Conducting public hearings on the rule proposal
- Completing a Small Business Economic Impact Statement and a Benefit - Cost Determination

L&I used a best-available-evidence approach throughout the rulemaking process in assessing the benefits, costs and feasibility of a mandatory cholinesterase-monitoring rule. Because cholinesterase monitoring is not routinely done in Washington State, evidence regarding the extent of cholinesterase depression and the efficacy of cholinesterase monitoring is not available. The best available evidence was considered

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<sup>5</sup> U.S Environmental Protection Agency. Worker Protection Standard, Final Rule. Federal Register, August 1992

<sup>6</sup> Technical Advisory Group Report: Cholinesterase Monitoring in Washington State. 1995. Washington State department of Labor & Industries

<sup>7</sup> *Juan Rios and Juan Farias v. Washington State Department of Labor & Industries et al.* 2002. Docket Number 70294-2. Supreme Court of the State of Washington.

to answer the questions of whether cholinesterase monitoring was appropriate and both technologically and economically feasible.

In deciding to adopt the cholinesterase-monitoring rule L&I has concluded that hurdles to implementing an effective program have been addressed and that cholinesterase monitoring is both technologically and economically feasible.

The following significant policy issues have been addressed:

*Who should receive medical monitoring?*

The rule scope covers agricultural employees who handle only toxicity category I or II organophosphate or N-methyl-carbamate pesticides. Handling activities are those activities listed under the definition of "handler" in WAC 296-307-11005. This is consistent with the recommendations contained in the *Rios* decision, L&I's cholinesterase monitoring recommendation, and the California cholinesterase-monitoring program.

*What is the appropriate exposure threshold?*

The 1993 L&I cholinesterase monitoring recommendation contained an exposure threshold for medical monitoring of handling organophosphate or N-methyl-carbamate pesticides for 30 or more hours in any 30-day period. This threshold was based on California's experience since 1974 and their determination that a 30-hour threshold was appropriate.

L&I asked for evidence that would indicate that a lower or higher exposure threshold would be more appropriate. No conclusive evidence was provided. The department has determined that a 30-hour in 30-day exposure threshold for medical monitoring is appropriate. However, the initial impacts will be mitigated during the first year by phasing in the rule with an exposure threshold of 50 hours in any consecutive 30-day period in 2004. The exposure threshold will become 30 hours in 2005. The department has decided to adjust the exposure threshold in 2005 if data collected during 2004 indicates that the threshold should be lower or higher than 30 hours.

*Should the use of closed mixing and loading systems be required?*

The rulemaking record does not contain sufficient evidence to require closed systems for mixing and loading pesticides. EPA is currently evaluating label requirements for closed systems with respect to the covered pesticides. However, the rule has an incentive effect for employers to increase their use of closed systems, both as a result of the desire to avoid depressions and the rule's exclusion of hours spent mixing and loading using closed systems from counting towards the periodic testing threshold. The benefit from an increased use of closed systems would be a reduction of accidental splash/spill exposures and employee illness partly or wholly due to these types of exposures.

*Should testing be conducted on employees whose sole exposure is to N-methyl-carbamate pesticides?*

N-methyl-carbamate and organophosphate pesticides share a similar mechanism of toxicity. They differ in that AChE has a much more rapid recovery after exposure to N-methyl-carbamates than it does from organophosphates. Reversal of the carbamate/cholinesterase bond is spontaneous and complete regeneration may occur in a matter of hours. Because of this monitoring on a 30 day basis would be of little benefit in detecting cholinesterase depression from N-methyl-carbamates. However, because organophosphates and N-methyl-carbamates share a mechanism of toxicity and the adverse effects of dual exposure can be additive, there is a direct benefit from considering N-methyl-carbamate exposure when determining exposure thresholds for cholinesterase testing. Therefore the cholinesterase-monitoring rule contains an exemption from testing employees whose sole exposure is to N-methyl-carbamate pesticides. The rule requires consideration of all employee handling hours, for both organophosphate and N-methyl-carbamate pesticides, to determine the need for testing.

*When should baseline testing be conducted?*

The rule requires baseline testing to be conducted at least 30 days after the employee's last handling of a cholinesterase inhibiting pesticide and is consistent with California's medical monitoring guidelines and ACGIH recommendations.

L&I decided to require annual baseline determinations. This decision was based on the intraindividual variability of cholinesterase levels and a concern that the recordkeeping logistics required for bi-annual baseline testing would be obstacles to effective medical monitoring and surveillance.

*How will comparability of test results be assured?*

Studies have shown a wide range of cholinesterase test results when different laboratories and different testing methodologies were used. In addition, test results may be reported using different units of measure, making comparisons of baseline and periodic tests difficult. California acknowledged this problem and has recently amended their cholinesterase-monitoring rule to include a standardized testing procedure.

L&I has concluded that this issue has been addressed by identifying a standardized testing methodology, requiring the use of the Department of Health Public Health Laboratory to run all of the cholinesterase tests during 2004 and 2005, and only allowing the use of department approved laboratories beginning in 2006.

*What is the appropriate frequency for periodic cholinesterase testing?*

The cholinesterase-monitoring rule requires that periodic testing be provided within 3 days of the end of any 30-day period in which the exposure threshold is met. Two

primary issues were considered in determining this schedule 1) that testing be conducted often enough to detect exposure to cholinesterase-inhibiting pesticides, and 2) that the testing schedule be simple enough to allow for compliance. Testing at 30-day intervals is sufficient to detect cholinesterase depression due to exposure to organophosphate or organophosphate and N-methyl-carbamate pesticides. California actually allows testing to be extended to 60-day intervals. However, L&I decided that it was prudent to require testing at 30-day intervals to provide consistent test data for rule evaluation purposes.

Allowing testing to be conducted on a routine basis allows the employer to either provide testing every 30 days whether or not the exposure threshold is met or only when the exposure threshold is met. The advantage to testing every 30 days regardless of whether or not the exposure threshold was met is that the employer does not need to calculate exposure hours at the end of each 30-day period. The advantage to testing only when the exposure threshold is met is that the employer may save money and worker time by not providing testing not required by the rule.

*What are the appropriate threshold values for medical removal?*

The World Health Organization (WHO), American Conference of Governmental Industrial Hygienists (ACGIH), and the National Institute for Occupational Safety and Health (NIOSH) have all recommended employee removal from further exposure to cholinesterase-inhibiting pesticides when red blood cell cholinesterase decreases 30% or more from baseline. The Washington rule's cholinesterase-monitoring requirement and California's rule use a 30% depression trigger for red blood cell cholinesterase and a 40% depression for plasma cholinesterase. L&I has determined that both the 30% depression trigger for red blood cell cholinesterase and 40% depression trigger for plasma cholinesterase are appropriate.

**Summary of the cholinesterase-monitoring rule**

The final rule includes the following provisions:

1. The employer will be required to keep records of all employee handling of covered pesticides, and retain those records for seven years.
2. Cholinesterase monitoring (RBC and plasma cholinesterase) will be required for employees who handle covered pesticides for 50 or more hours in any consecutive 30-day period beginning February 1, 2004, and for 30 or more hours in any consecutive 30-day period beginning February 1, 2005.
3. Employers will be required to ensure that employees requiring medical monitoring will receive training that includes at a minimum:
  - The human health hazards associated with exposure to organophosphate and N-methyl-carbamate pesticides
  - The purpose and requirements of cholinesterase monitoring.

4. Employers will identify a medical provider to provide (at no cost to the employee, and at a reasonable time and place) baseline and periodic testing, interpretation of test results, and recommendations resulting from those test results
5. Employees may choose to decline cholinesterase testing after receiving training and consulting with the medical provider.
6. Pre-exposure baseline testing will be conducted annually.
7. Employers with employees who handle only N-methyl-carbamate pesticides will be exempt from the requirement to offer those employees cholinesterase testing.
8. Hours spent mixing and loading using closed systems (as described in WAC 296-307-13045(4)(d)) will not be counted as exposure hours for the purposes of periodic testing.
9. Periodic testing will be required within 3 days of meeting the designated exposure thresholds or at least every 30 days while exposure is expected to exceed thresholds.
10. Cholinesterase depressions will require the following employer actions:
  - A depression of more than 20% from the employee's personal baseline will require the employer to conduct a work practice evaluation.
  - An RBC cholinesterase depression of 30% or more from the personal baseline or a plasma cholinesterase depression of 40% or more from the personal baseline will require the employee to be temporarily removed from organophosphate and N-methyl-carbamate exposure and the employer to conduct a work practice evaluation.
  - An employee removed from exposure will not be allowed to return to handling of covered pesticides or participate in other activities with exposure until his or her cholinesterase levels are within 20 percent of the personal baseline.
11. Medical removal protection will be made available to employees removed from handling due to cholinesterase depression, until the employee is able to return to normal duties (not to exceed 3 months).
12. The employer must provide for the maintenance of testing and related medical records for 7 years.
13. The exposure thresholds in the rule will be evaluated by L&I (in consultation with both a scientific panel and a stakeholder advisory group) before the 30-hour threshold takes effect and again before the third year of the rule's existence. L&I will propose changes to the rule if appropriate based on these evaluations.

## **Conclusion**

L&I conducted a Small Business Economic Impact Statement (SBEIS) of the proposed rule and a Benefit Cost Determination (BCD) of the final rule. The SBEIS concluded that there would be a disproportionate impact on small business only in the professional applicator sector, beginning in the second year of rule implementation. The rule contains several mitigations to reduce the impact of the rule on small businesses without compromising worker protection.

Because cholinesterase monitoring is not currently being routinely performed in Washington State it is difficult to calculate specific quantitative benefits. The BCD did identify a range of benefits, primary among them being protection of worker health and prevention of serious illness and reduction of uncertainty regarding the number of poisoned workers in the state. After considering the statutory mandates of the Washington Industrial Safety and Health Act (WISHA), the guidance provided by the State Supreme Court in the Rios decision that prompted the rulemaking, and the best available evidence in the rulemaking record, L&I has determined that the benefits of the rule outweigh its probable costs, and that a statewide cholinesterase monitoring program is economically and technologically feasible.

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## WAC 296-307-148, Cholinesterase Monitoring

### THIS RULE IS BASED ON WELL SETTLED LEGAL PRINCIPLES

The Washington State Department of Labor and Industries (L&I) has adopted this workplace cholinesterase-monitoring rule to establish requirements for employers to identify employees with depressed cholinesterase levels and to take measures to make sure employees with depressed levels do not develop symptomatic cholinergic poisoning. Acetylcholinesterase (AChE) is an enzyme that aids in the regulation of the nervous system by removing the neurotransmitter acetylcholine from neuronal junctions and target receptor sites (for example, a muscle or gland). Organophosphate and N-methyl-carbamate pesticides (herein after “covered pesticides”) inhibit the activity of AChE. Exposure to covered pesticides can lead to an accumulation of acetylcholine, which in turn would result in the over-stimulation of an individual’s nervous system. Symptomatic cholinergic poisoning generally occurs when the levels of AChE drop below 50% of an individual’s baseline AChE level.<sup>8</sup> Common symptoms of such cholinergic poisoning include increased sweating, blurred vision, diarrhea, tremors and malaise. Severe exposures may result in pulmonary edema, respiratory distress, seizures, loss of consciousness, and death.

The statutory provision of the Washington Industrial Safety and Health Act (WISHA) being implemented requires L&I to adopt rules that “[p]rovide for the promulgation of health and safety standards and the control of conditions in all work places concerning gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents which shall set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life; any such standards shall require where appropriate the use of protective devices or equipment and for monitoring or measuring any such gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents.”<sup>9</sup> In addition, the statute provides that “where appropriate, any such rule shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure.”<sup>10</sup>

These provisions, and the language in the federal Occupational Safety and Health Act (OSHA) on which the Washington law is based, have been addressed several times by state and federal courts. The case that prompted this rulemaking, *Rios et al. v. Washington Department of Labor and Industries, et al.*, involved a farm workers’

<sup>8</sup> Fillmore CM & Lessenger JE. A cholinesterase testing program for pesticide applicators. Journal of Occupational Medicine. 1993; (35)1: 61-70.

<sup>9</sup> RCW 49.17.050(4).

<sup>10</sup> RCW 49.17.220(2)

challenge that the Department's failure to promulgate mandatory blood test monitoring was arbitrary and capricious.<sup>11</sup> The Washington State Supreme Court agreed. In a 7-2 decision, the Court found that the Department's 1997 denial of the pesticide handlers' request to require mandatory blood testing was arbitrary and capricious because: 1) the Department had already invested its resources in studying cholinesterase-inhibiting pesticides, and 2) the report of its own team of technical experts had, in light of the most current research, deemed a monitoring program both necessary and doable.<sup>12</sup> The Court therefore concluded that, in failing to act on the request for rulemaking, the Department violated RCW 49.17.050(4), which requires the Department to "set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health."<sup>13</sup>

The *Rios* court stopped short of ordering adoption of the rule, instead ordering L&I "to initiate rulemaking on a mandatory cholinesterase monitoring program for agricultural pesticide handlers..." and remanded the issue to L&I "for further proceedings *consistent with this opinion...*"<sup>14</sup> (emphasis added). The *Rios* court additionally provided guidance on the statutory requirement that health standards "set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health." The Court stated that "to the extent feasible" means "to the extent the standard is capable of being economically and technologically accomplished."<sup>15</sup> The Court additionally stated that "the critical language in the general definition of safety and health standard – 'reasonably necessary or appropriate' -- works in tandem with the economic feasibility analysis to set a limit on the adoption of feasible methods."<sup>16</sup> The Court further provided that additional standards are reasonably necessary or appropriate "so long as the additions are feasible, but only up to the point where additional ones are no longer necessary to protect against the 'worker's material impairment of health...'"<sup>17</sup> Finally, the Court stated that the Department's rulemaking process must consider whether:

- a significant risk of pesticide poisoning exists,
- a medical monitoring program is an appropriate method to help reduce that risk, and
- such a program is technologically and economically feasible.

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<sup>11</sup> 145 Wn.2d 483, 39 P.3d 961 (2002)

<sup>12</sup> *Id.* at 507-508.

<sup>13</sup> *Rios*, 145 Wn.2d at 507-508.

<sup>14</sup> *Id.* at 508-509.

<sup>15</sup> *Id.* at 498-99.

<sup>16</sup> *Id.* at 499-500.

<sup>17</sup> *Id.* at 500.

## **Best Available Evidence**

Regulatory agencies are sometimes able to make public policy decisions based upon readily observable and uncontestable facts without the need for scientific induction or deduction. For example, unguarded power saws present workplace hazards that are sufficiently obvious to warrant protective rules without extensive scientific study. However, for many workplace hazards the connection between initial exposure and eventual adverse outcome is less apparent. For example, lung cancer caused by asbestos typically does not appear for many years after the initial exposure. When faced with health effects that have a gradual or chronic onset or that result from repeated exposures to low levels of a toxic substance, regulatory agencies cannot rely exclusively on common sense or short-term observation but must use rely upon available scientific research to reach conclusions about significant risk and cause and effect.

The process of drawing conclusions from scientific evidence always involves some degree of uncertainty. This uncertainty has two sources. First, observational or experimental studies provide statistical evidence and inferences based on this evidence. Second, the scientific process requires making general conclusions based upon specific results. Full consensus among scientists is unusual. The relevant question for regulatory agencies is not whether a body of science is definitive and unchallenged, but whether it is sufficiently reliable and consistent to serve as the basis for public policy.

Recognizing the limitations of the data available to support regulation of safety and health risks, Congress and the Washington legislature directed that they be regulated on the basis of the “best available evidence.”<sup>18</sup> Where scientific or other technical information “is on the frontiers of scientific knowledge” and “the factual finger points, but does not conclude” it “remains the duty of the [agency] to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient.”<sup>19</sup> The “best available evidence” standard suggests that safety and health regulation is appropriate where the Agency “can make reasonable predictions on the basis of credible sources of information.”<sup>20</sup>

The rulemaking record contains criticisms that scientific studies are limited in number, have methodological weaknesses, or fail to prove a relationship between organophosphate and N-methyl-carbamate pesticide exposures in Washington

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<sup>18</sup> L&I’s legal analysis relies, where applicable, on case law interpreting the Occupational Safety and Health Act, whose provisions are nearly identical to those of the Washington Industrial Safety and Health Act. L&I views the legal burdens placed upon it to be similar to those placed on OSHA, except insofar as the Washington State courts have ruled otherwise (e.g. *Aviation W. Corporation v. Dep’t of Labor & Indus.*, 138 Wn.2d 413, 980 P.2d 701 (1999)). References to OSHA’s legal obligations are matched by similar obligations for L&I.

<sup>19</sup> *The Society of Plastics Industries v. OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975).

<sup>20</sup> *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1266 (D.C. Cir. 1981). If OSHA were required to delay regulation until a scientific consensus was achieved, significant harm to workers from latent hazards already would have occurred. Cf. *Industrial Union Department v. American Petroleum Inst.*, 448 U.S. 607 (1980) (noting that OSHA regulation need not wait until deaths have occurred).

workplaces and cholinesterase depression. Such criticism “fundamentally misconstrues” the role of regulatory agencies because it misrepresents “the contribution that each piece of evidence makes to the whole picture....”<sup>21</sup> While some studies may have limitations or inconsistencies, “such incomplete proof is inevitable when the Agency regulates on the frontiers of scientific knowledge.”<sup>22</sup> When faced with cumulative evidence: “[OSHA] need not seek a single dispositive study that fully supports [its] determination. Science does not work that way... Rather, [OSHA’s] decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion...”<sup>23</sup>

It is not appropriate to delay regulation until a scientific consensus emerges on the incidence of cholinesterase depression in Washington State. Congress and the Washington legislature adopted the “best available evidence” standard so regulation of workplace risks would not have to await scientific consensus. Congress did not want OSHA to “be paralyzed by debate within the scientific community.”<sup>24</sup> Congress feared OSHA regulation dependent on consensus within the scientific community would represent “the lowest common denominator of acceptance by interested private groups.”<sup>25</sup> By adopting the identical standard in the WISH Act, the Washington State Legislature confirmed its intent to ensure that L&I is likewise not paralyzed by lack of consensus in the scientific community.

## Health Effects

L&I is mandated to regulate “material impairments to worker health and functional capacity.”<sup>26</sup> Cholinesterase depression represents a continuum of health effects, ranging from no discernable symptoms to severe overt symptoms that represent material impairment of worker health.

Covered pesticides share a common mechanism of toxicity. Both bind with AChE and thereby, prevent destruction of acetylcholine. The major difference between covered pesticides is that the phosphate bond with AChE persists for days and may become permanent, while the carbamate bond with AChE may last for only a few hours to a day. In general, regeneration (replacement) of permanently bound AChE is measured at the rate that AChE is synthesized in the production of new red blood cells (approximately 1 percent per day).

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<sup>21</sup> *Public Citizen v. Tyson*, 796 F.2d 1479, 1495 (D.C. Cir. 1986).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 37-38 (D.C. Cir. 1976)(en banc), *cert. denied*, 426 U.S. 941, 96 S.Ct. 2663, 49 L.Ed.2d 394 (1976).

<sup>24</sup> Occupational Safety and Health Act Legislative History at 848.

<sup>25</sup> Occupational Safety and Health Act Legislative History at 146.

<sup>26</sup> RCW 49.17.50(4)

While the inhibition of AChE by Organophosphate pesticides lasts much longer than inhibition by N-methyl-carbamate pesticides, the physiologic consequences of poisoning by the two categories of pesticides have the same toxic effect. Overlapping exposures to the two categories of pesticides can result in an accumulation of toxic effects. Therefore it is appropriate to include dual exposure to organophosphate and N-methyl-carbamate pesticides when determining testing trigger levels.

L&I has concluded that a significant risk exists. L&I is not required to wait for the most serious outcomes before regulating. L&I may take action aimed at early, reversible and less severe health effects to prevent the most serious and life threatening health effects.<sup>27</sup> The federal courts recognize that OSHA may impose monitoring and medical surveillance requirements even if it is unsure that a significant risk exists.<sup>28</sup> OSHA may do so (1) to check the validity of its assumptions, (2) to develop evidence for a revised standard, or (3) to protect susceptible workers from harm.<sup>29</sup> Therefore, even if L&I had concluded that existing pesticide rules may have eliminated significant risk, it would still be reasonable for L&I to require medical monitoring for the covered pesticides, to ensure workers are protected from serious and life threatening health effects.

Safety and health standards must be reasonably addressed toward a widespread workplace hazard and be effective at reducing exposure to that hazard. The applicable standard in Washington, adopted by the Washington Supreme Court in *Aviation West et al. v. Labor and Industries*,<sup>30</sup> provides that rules must be “reasonably necessary or appropriate.” In *Aviation West*, the State Supreme Court rejected a strict reading of the *United Steelworkers of America v Marshall* plurality opinion advocated by the tobacco companies. Instead, the court adopted Justice Marshall’s dissent, which gave OSHA broad discretion in enacting rules provided that they are “reasonably necessary or appropriate.”

*Aviation West* requires a finding that: (1) the hazard the rule proposes to regulate is a sufficiently widespread or severe workplace risk to warrant government intervention; and (2) the rule will be effective at reducing or eliminating exposure to the hazard. The *Aviation West* Court stated that “neither the existence of contradictory evidence nor the possibility of deriving conflicting conclusions from the evidence renders an agency decision arbitrary and capricious.”<sup>31</sup>

Accepted methods of cholinesterase monitoring involve measuring the activity of both red blood cell (RBC) and plasma cholinesterase. Both blood enzymes have been shown to act as surrogates for AChE activity in the nervous system.<sup>32</sup> Although RBC cholinesterase is the same AChE found in the nervous system and is thought to better

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<sup>27</sup> See *United Steelworkers of America v. Marshall*, 647 F.2d at 1266; *AFL-CIO v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), aff’d *American Textile Mfrs Instutet v. Donovan*, 452 U.S. 490, 101 S.Ct. 2478, 69 L.Ed.2d 185 (1981).

<sup>28</sup> *National Contonseed Prods. v. Brock*, 825 F.2d 482, 486, 13 OSH Cases 1353 (D.C. Cir. 1987).

<sup>29</sup> *Id.*

<sup>30</sup> 138 Wn.2d 413, 980 P.2d 701 (1999).

<sup>31</sup> *Id.* at 429.

<sup>32</sup> Environmental Protection Agency. The use of data on cholinesterase inhibition for risk assessments of organophosphorus and carbamate pesticides. 2000. Office of Pesticide Programs.

reflect effects on nervous system, it is more difficult to measure and is depressed more slowly than plasma cholinesterase. Some pesticides preferentially lower the activity of either enzyme. For example, chlorpyrifos lowers plasma cholinesterase activity while phosmet and dimethoate preferentially lower RBC cholinesterase. Since each of these has different characteristics, measuring both RBC and plasma cholinesterase enzymes will give a more accurate assessment of the cholinesterase activity level and any possible exposure.<sup>33</sup>

Blood cholinesterase measurement is subject to intra and interpersonal variability. Because of this variability, there is no “normal” cholinesterase level. This means that effective monitoring depends upon a periodic comparison of an individual’s cholinesterase levels to a personal baseline value established, for that individual, prior to exposure. Because of expected variability, the rule does not require an employer response to a cholinesterase depression until a meaningful reduction from the personal baseline has been identified.

Monitoring blood cholinesterase levels will detect workplace exposures that contribute to cholinesterase depression. The cholinesterase-monitoring rule is structured so employers are responsible only for reducing hazardous workplace exposures that contribute to employee cholinesterase depression. While non-workplace exposures to the pesticides covered by the rule may occur, the rule does not regulate these non-workplace exposures. So long as a WISHA regulation addresses workplace harms, and limits employer abatement to workplace conditions, intervention is proper.

Regulation in situations where there is workplace and non-workplace exposure was upheld in *Forging Industries Association v. Secretary of Labor*. The court in that case rejected industry’s argument that OSHA exceeded its authority by regulating hearing loss -- an effect that can be caused by aging and exposures outside the workplace.<sup>34</sup> The court upheld the standard because it “ensure[d] that a hearing endangered worker is provided with protection in the workplace in order to decrease the risk of a hearing impairment. Having identified employee susceptibility to noise the Act does not wait for an employee to become injured. It authorizes the promulgation of health and safety standards in the hope that these will act to prevent injuries from occurring.”<sup>35</sup>

Exposure to environmental tobacco smoke (ETS) posed the same concern. Before L&I promulgated its ETS standard, employees in office environments faced exposure to ETS at work and outside of work. Both exposures contribute to lung cancer. Reducing workplace exposures does not completely eliminate the risk of lung cancer if an employee’s non-work exposures continue. Nevertheless, regulation of workplace ETS was upheld.<sup>36</sup> Even in situations where there is a synergistic relationship between work

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<sup>33</sup> California Environmental Protection Agency. Guidelines for physicians who supervise workers exposed to cholinesterase-inhibiting pesticides. 2002. Office of Environmental Health Hazard Assessment.

<sup>34</sup> *Forging Industries Association v. Secretary of Labor*, 773 F.2d 1436, 1442-43 (4<sup>th</sup> Cir. 1885)(en banc)

<sup>35</sup> *Id.*

<sup>36</sup> See generally, *Aviation West*, 138 Wn.2d 413, 980 P.2d 701 (1999)

and non-work exposures (e.g. asbestos and tobacco smoke), the agency still has good reason and a duty to regulate the workplace contribution to risk.

## Feasibility

WISHA rules must be feasible. Feasibility has two elements: the technological ability of affected firms to reduce hazardous exposures and the financial ability of the affected industry to absorb the costs of such controls.

A standard is technologically feasible if L&I, like OSHA, demonstrates a reasonable possibility that the mechanisms for implementing the regulation exist or can be developed. Cholinesterase monitoring is an accepted method for evaluating employee exposure to organophosphate and N-methyl-carbamate pesticides. The ACGIH includes this method in their recommendations for Biological Exposure Indices<sup>37</sup> and California has conducted a cholinesterase-monitoring program for agricultural workers since 1974. WISHA will approve laboratories to perform blood cholinesterase analysis and initially only the State Public Health Laboratory will be approved to conduct blood cholinesterase analysis. The use of the Public Health Laboratory will eliminate many laboratory quality control issues during initial testing and facilitate establishing the Public Health Laboratory as a reference laboratory for additional laboratories that are subsequently approved.

The test of economic feasibility is well settled. As the D.C. Circuit explained in *United Steelworkers v. Marshall* a standard is not economically infeasible “simply because it is financially burdensome.”<sup>38</sup> Even where the predicted costs of compliance with a standard are “initially frightening” courts require OSHA to “examine those costs in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices.”<sup>39</sup> The practical question is whether the standard “threatens the competitive stability of an industry or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration.”<sup>40</sup>

To prove economic feasibility, the court “probably cannot expect hard and precise estimates of costs” particularly where OSHA predicts a firm’s technological capacity to comply. OSHA must, however, make a “reasonable assessment of the likely range of costs and the likely effects of those costs on the industry.”<sup>41</sup>

In developing cost estimates, OSHA can revise numbers submitted to it by industry. It can eliminate sources of double counting. It can assume industry compliance with existing law. OSHA’s cost estimate must reflect the incremental cost of increased

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<sup>37</sup> American Conference of Governmental Industrial Hygienists (ACGIH) Documentation of the Threshold Limit Values (TLV) for Chemical Substances and Physical Agents & Biological Exposure Indices (2003)

<sup>38</sup> *United Steel Workers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980).

<sup>39</sup> *Id.*

<sup>40</sup> *Industrial Union Department v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974).

<sup>41</sup> *United Steelworkers of America v Marshall*, 647 F.2d at 1266.

regulation; expenses that would be incurred in the absence of regulation are not properly attributed to the rule. OSHA may group “large categories of industries together” so long as it provides “some explanation of why findings for the group adequately represent the different industries in that group.”<sup>42</sup>

L&I finds the cholinesterase-monitoring standard is technologically and economically feasible in all affected industries. The technology to monitor employee acetylcholinesterase levels is readily available to business through the medical community. Further, the phased implementation of this rule creates an opportunity for more clearly defining the worker population at risk and the workplace conditions that are hazardous, allowing the rule to be focused on those exposures presenting an actual risk to employees.

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<sup>42</sup> *AFL-CIO v. OSHA*, 965 F.2d 962 (11<sup>th</sup> Cir. 1991).

## **EVIDENCE FOR MATERIAL IMPAIRMENT FROM WORKPLACE EXPOSURE TO ORGANOPHOSPHATE AND N-METHYLCARBAMATE PESTICIDES.**

### **Cholinesterase depression is a serious ailment**

The toxic signs and symptoms associated with exposure to the covered pesticide compounds are related to inhibition of the enzyme acetylcholinesterase (AChE) at the junctions (gaps) between nerves and target sites (muscles, glands, organs). The transmission of nerve impulses across these junctions is accomplished by the release of the chemical neurotransmitter, acetylcholine. When an impulse travels through a nerve, acetylcholine is released into the junction and destroyed by AChE almost instantly. Acetylcholine does not persist or accumulate in the junctions. Normal function of the nervous system relies on the rapid destruction of acetylcholine by AChE. If AChE activity is inhibited, acetylcholine will accumulate at the junctions and may result in over stimulation or exhaustion of target sites. For example, initial inhibition of AChE may result in muscle twitching while continued inhibition results in muscle weakness<sup>43</sup>.

The toxic effects of covered pesticides are related to the inhibition of AChE in the central and peripheral nervous systems. Although covered pesticides share a similar mechanism of toxicity, they differ in the specific manner in which they inactivate AChE. Organophosphates bind with AChE through a process called phosphorylation. Regeneration of the phosphorylated enzyme may take days to months. A portion of phosphorylated cholinesterase may become permanently combined. In this case the enzyme must be replaced through production of new enzyme. On the other hand the carbamate/cholinesterase bond is readily reversible and cholinesterase levels may return to preexposure levels in matter of hours.

Because of their common mechanism of toxicity, overexposure to covered pesticides produce similar clinical signs and symptoms. Initial symptoms can occur within minutes to hours of significant exposures. Early signs of poisoning include headache, constriction of the pupils, muscle fasciculation, diarrhea, and excess urination, tearing, and salivation. Severe cases of poisoning may result in tremors, convulsions, coma, respiratory paralysis and even death<sup>44</sup>. Although there is no specific threshold of cholinesterase depression that is associated with clinical illness, overt signs and symptoms are usually apparent when depressions reach 50% of an individuals' baseline. The cholinesterase-monitoring rule is designed to identify depressions in cholinesterase levels that indicate exposure and allow for intervention before symptoms of cholinergic poisoning occur.

<sup>43</sup> Hayes, W.J. & Laws, E.R, 1991. Handbook of Pesticide Toxicology. Academic Press, San Diego, CA

<sup>44</sup> Wilson, B. (2001). Handbook of Pesticide Toxicology: Cholinesterases. Academic Press. New York, NY

Potential long-term effects of exposure to cholinesterase-inhibiting pesticides are being researched. Organophosphates may damage nerve cell fibers resulting in a delayed syndrome called organophosphate-induced delayed neuropathy (OPDIN), and this is manifested by weakness or paralysis and paresthesia of the extremities. OPDIN may persist for weeks to years. In addition, an intermediate syndrome has been described. This syndrome generally occurs within 24-96 hours after exposure. It is characterized by respiratory paresis and muscle weakness.<sup>45</sup> Other research has established possible relationships between exposure to cholinesterase-inhibitors and changes in cognitive (e.g., concentration, memory, and language) function.<sup>46</sup>

Acute exposures to cholinesterase-inhibiting pesticides may require medical treatment and hospitalization. Fortunately, because cholinesterase depression is often reversible, most inhibitions of cholinesterase activity can be treated by simply removing the individual from further exposure to cholinesterase inhibiting compounds until cholinesterase levels return to within normal range. Medical monitoring that consists of periodic measurements of cholinesterase activity levels in the blood compared to measurements of baseline cholinesterase activity levels, has been shown to be effective in identifying and protecting workers who have been overexposed to organophosphate and carbamate pesticides.<sup>47</sup>

**Literature Summary –** The scientific research that has examined the health effects of exposure to organophosphate and N-methyl-carbamate cholinesterase inhibiting pesticides shows a strong relationship between cholinesterase depression and clinical illness. Routine medical monitoring, that includes cholinesterase blood level determinations, has the ability to detect significant cholinesterase depressions before the onset of illness.<sup>48</sup> A summary of the literature on this topic is provided below:

1. Weinbaum Z., Schenker MB, O'Malley, MA, Gold EB, & Samuels SJ. (1995). Determinants of Disability in Illnesses Related to Agricultural use of Organophosphates (Ops) in California. American Journal of Industrial Medicine, vol. 28(2); 257-274

Organophosphate (OP)-related illness data reported to the Worker Health and Safety Branch at the California Department of Food and Agriculture in the years 1984-1988 were examined. Eight hundred and seventy-eight cases with systemic illness and 199 cases of skin or eye injury were identified. Workers coming in contact with OP residue and mixer/loader/applicators were at significantly increased risk of severe illness. Cases with Spanish surnames were also at increased risk of severe illness. Findings suggest that reducing exposure to OP residues, to Ops with

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<sup>45</sup> Recognition and Management of Pesticide Poisonings, 5<sup>th</sup> Edition. 1999, EPA

<sup>46</sup> Keifer, M.C. & Mahurin, R.K. 1997. Occupational Medicine: State of the Art Reviews

<sup>47</sup> Ames. R.G. & Menendez, R., 1999. Results of a Survey regarding Certification and Training for Physicians Providing Medical Supervision for California Pesticide Mixer/Loader/Applicators. California Environmental Protection Agency

<sup>48</sup> Guidelines for physicians who supervise workers exposed to cholinesterase-inhibiting pesticides, California Office of Environmental Health Hazard Assessment, 2002

diethyl groups, and to multiple Ops, and to exposure during mixer/loader/applicator activities would reduce the risk of OP-related illness.

2. Environmental Protection Agency (2000). The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides. Office of Pesticide Programs, Washington, DC.

This science policy statement uses a weight-of-evidence assessment of cholinesterase-inhibiting substances; acetylcholinesterase inhibition in the nervous system is viewed as a key event in the mechanism of toxicity of these compounds and an important critical effect to consider in a (pesticide) hazard assessment. Evaluations of cholinergic effects (i.e., physiological and behavioral changes and measures of cholinesterase inhibition in the central and peripheral nervous systems) caused by exposure to the cholinesterase-inhibiting organophosphorous and carbamate pesticides provide direct evidence for characterizing potential human health hazards.

3. Reigart R. & Roberts J. (1999). Recognition and Management of Pesticide Poisonings, 5<sup>th</sup> Edition. United State Environmental Protection Agency, Washington, DC

Describes many of the adverse acute and longer-term effects of exposure to organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides and their clinical management. Signs and symptoms are cholinergic in nature affecting both the central and peripheral nervous system cholinergic pathways. Most commonly reported in humans are headache, nausea, and dizziness. Anxiety and restlessness are prominent. Muscle twitching weakness, tremor, incoordination, vomiting, and diarrhea all signal worsening of the poisoned state. Confusion, bizarre behavior, and toxic psychosis may occur. In severe poisonings, toxic myocardiopathy, unconsciousness, incontinence, convulsions, respiratory depression and death may be seen. Repeated absorption, but not enough to cause acute poisoning may result in persistent anorexia, weakness, and malaise.

4. Keifer M. & Mahurin R. (1997). Chronic Neurological Effects of Pesticide Exposure. Occupational Medicine: State of the Art Reviews. Hanley & Belfus, Inc. Philadelphia, PA

The researchers describe some of the most important examples of established pesticide neurotoxicity as presented in case reports and studied in peer reviewed literature. Chronic physical effects of exposure to organophosphate and carbamate cholinesterase-inhibiting pesticides include peripheral neuropathies, altered reflexes, and nerve conduction abnormalities. Cognitive effects of exposure include impairments in vigilance, concentration, information processing, psychomotor speed, memory, and language. Chronic effects of exposure where more frequently associated with organophosphate pesticides.

5. Lessenger J.E. & Benjamin RE. (2000). The Pathophysiology of Acetylcholinesterase Inhibiting Pesticides. *Journal of Agromedicine*, 7(2).

The article reviews the physiology of cholinesterase transmission as it relates to pesticide poisoning. Interference with cholinergic transmission is presented as the primary factor in the pathophysiology of cholinesterase –inhibiting pesticides. The authors further recommend the use of cholinesterase testing for monitoring exposure and defining safe exposure limits. Evidence showing chronic long-term effects following low-level exposure is reviewed.

6. Savage EP, Keefe TJ, Mounce LM, Heaton RK, Lewis JA, Burcar PJ. (1988). Chronic Neurological Sequelae of Acute Organophosphate Pesticide Poisoning. *Archives of Environmental Health*, vol. 43(1). Springer-Verlag, Heidelberg, Germany

This study was conducted to determine whether persons with previous documented acute organophosphate pesticide poisonings exhibited covert manifestations of latent chronic neurological deficits. The study was conducted using 100 matched pairs to compare a cohort of 100 cases previously poisoned by organophosphate pesticides to 100 controls. The results of the study indicate that there are chronic neurological sequelae to acute organophosphate poisoning. Differences were found in the areas of intellectual functioning, academic skills, abstraction, flexibility of thinking, and simple motor skills.

7. O'Malley MA & McCurdy, S.A. (1988). Subacute Poisoning with Phosalone, an Organophosphate Insecticide. *Western Journal of Medicine*, 153; 619-624

The authors reviewed an episode of reported illness characterized by weakness, dizziness, and gastrointestinal symptoms among a crew of 30 migrant field-workers. Symptoms occurred a median of 9 days from first employment. 10 crewmembers were admitted to the hospital and 4 crewmembers had episodes of severe sinus bradycardia persisting for several days. Of 20 crewmembers who had cholinesterase levels tested all had moderate to severe inhibition of both plasma and red blood cell cholinesterase. The crewmembers all had exposure to the organophosphate pesticide phosalone which was applied to the field 29 days prior to initial exposure.

8. Wassailing C, Keifer MA, Ahlbom A, Mcconnell R, Moon J, Rosenstock, L., & Hogstedt, C. (2002). Long-term Neurobehavioral Effects of Mild Poisonings with Organophosphate and N-methyl-carbamate Pesticides among Banana Workers. *International Journal of Occupational and Environmental Health*, 8(1); 27-34.

This study looks at the long-term neurobehavioral effects of exposure to organophosphate and n-methyl-carbamate pesticides with particular focus on establishing a relationship with n-methyl carbamate poisoning. This cross-sectional study evaluated the neurobehavioral performances of 81 banana workers who had previously received medical attention for mild occupational poisoning by either an

organophosphate or n-methyl-carbamate pesticide. These performances were compared to 130 banana workers who had never sought medical attention for pesticide poisoning. Poisoned subjects did less well than controls on tests measuring psychomotor and visomotor skills, language function, and affect. These deficits were most apparent among the organophosphate poisoned subjects, but small deficits in performance were also seen in the carbamate-poisoned subjects.

9. Das R, Steege A, Baron S, Beckman J, & Harrison R. (2001). Pesticide-related Illness among Migrant Farm Workers in the United States. International Journal of Occupational and Environmental Health, vol. 7(4); 303-312.

Surveillance data show that pesticide-related illness is an important cause of acute morbidity among migrant farm workers in California. A few categories (organophosphate and carbamates, inorganic compounds, and pyrethroids) account for over half of the cases of acute illness. Skin effects are most common, followed by nervous system and gastrointestinal symptoms. Nearly a third of the farm workers reported in the California Department of Health services surveillance system lost eight hours or more from work as a result of pesticide-related illness. Over a fourth of farm-worker related illnesses reported in 1988-99 occurred from exposures while mixing, loading, or applying pesticides.

10. Wilson B. (2001). In the Handbook of Pesticide Toxicology: Cholinesterases. Academic Press. New York, NY

The author presents a concise overview of the toxicology and pathophysiology of cholinesterase inhibiting pesticides, along with a description of current enzyme screening methodologies. Organophosphate and carbamate pesticides inhibit enzyme (cholinesterase) activity by acting as alternate substrates to acetylcholinesterase. Many physiological actions of anti-cholinesterases are those expected from excess acetylcholine caused by inhibition of its catalysis (removal). Symptoms include slowing of the heart, constriction of the pupil, diarrhea, urination, lacrimation, and salivation. Over stimulation of the skeletal muscles causes fasciculation and, at higher doses, muscular paralysis. Anti-cholinesterases also affect the central nervous system, producing hypothermia, tremors, headache, anxiety, convulsions, coma, and death.

11. Coye MJ, Barnett PG, Midtling JE, Velasco AR, Romero P, Clements CL, & Rose TG. (1987). Clinical confirmation of organophosphate poisoning by serial cholinesterase analyses. Archives of Internal Medicine, vol. 147(3); 438-442.

In this study three groups of agricultural workers with a history of exposure to organophosphate pesticides were followed up to evaluate the utility of sequential post-exposure cholinesterase analyses to confirm organophosphate intoxication in the absence of baseline cholinesterase values. Three or more cholinergic symptoms were reported by 50 of the 72 patients. Initial plasma and red blood cell cholinesterase values of 45 of the workers were above the lower limit of the

laboratory normal range. Follow-up examinations, including cholinesterase analyses, were conducted on 57 patients. When final post exposure cholinesterase determinations were taken as estimates of individual normal baseline values, the plasma and red blood cell activity of the three groups was shown to have been inhibited. The data support the use of sequential post exposure plasma cholinesterase analyses to confirm the diagnosis of organophosphate-induced illness in the absence of baseline values.

12. Fillmore CM & Lessenger JE. (1993). A Cholinesterase Testing Program for Pesticide Handlers. *Journal of Occupational Medicine*, vol. 35(1); 61-70.

The authors report on the State of California's cholinesterase monitoring program for pesticide applicators. In this retrospective cohort study, 103 worker-years of cholinesterase monitoring are reported. Twenty-four (24%) workers were temporarily removed from spraying (five were removed twice) because their cholinesterase plasma activity levels were below 60% of baseline. Five workers (5%) had mild symptoms of toxicity but none reported a specific incident of exposure. The relative risk of pesticide poisoning was increased in workers whose initial plasma levels were low or if their levels had already dropped to 60-80% of their baseline previously in the season. Case studies and differences in baselines by month of determination suggest poor monitoring compliance by the companies and employees. Suggestions of how the physician can overcome these problems and improvements of the guidelines are discussed,

13. Ames RG, Brown SK, Mengle DC, Kahn E, Stratton JW, & Jackson RJ. (1989). Cholinesterase Activity Depression among California Agricultural Pesticide Applicators. *American Journal of Industrial Medicine*, vol. 15(2); 143-150.

Cholinesterase activity measurements for 542 California agricultural pesticide applicators under medical supervision during the first nine months of 1985 were analyzed. Twenty-six workers, 4.8% of the sample, had cholinesterase values at or below the California threshold values for removal from continued exposure to cholinesterase-inhibiting pesticides (60% of baseline for red blood cell cholinesterase and 50% of baseline for plasma cholinesterase activity). Eight of these 26 workers, 31.5% had pesticide related illnesses. Pesticides most frequently associated with cholinesterase depressions exceeding California's threshold values included mevinphos (Phosdrin), oxydemeton methyl (Metasystox-R), methomyl (Lannate), and acephate (Orthene); these pesticides included organophosphates in toxicity categories I and II and one carbamate in toxicity category I.

14. Zheng T, Zahm SH, Cantor KP, Weisenburger DD, & Blair A. (2001). Agricultural Exposure to Carbamate Pesticides and Risk of Non-Hodgkin Lymphoma. *Journal of Occupational and Environmental Medicine*, vol. 43(7); 641- 649.

This study examined the suggested relationship between an increased risk of non-Hodgkin Lymphoma (NHL) from carbamate insecticide use among farmers. The

authors conducted a pooled analysis of three population-base case-control studies conducted in four Midwestern states in the United States. A total of 985 white male subjects and 2895 control subjects were included in this analysis. Compared with nonfarmers, farmers who had ever used carbamate pesticides had a 30% to 50% increased risk of NHL, whereas farmers without carbamate pesticide use showed no increased risk. Analysis for individual carbamate pesticides found a more consistent association with Sevin but not for carbofuran, butylate, or S-ethyl dipropylthiocarbamate plus protectant. Among farmers using Sevin, the risk of NHL was limited to those who personally handled the product, those who first used the product for > or =20 years before their disease diagnosis, and those who used the product for a longer period. These associations persisted after adjusting for other major classes of pesticides. These results suggest an increased risk of NHL associated with carbamate pesticide use, particularly Sevin.

15. Ciesielski S, Loomis DP, Mims SR, & Auer A. (1994). Pesticide Exposures, Cholinesterase Depression, and Symptoms among North Carolina Migrant Farmworkers. *American Journal of Public Health*, vol. 84(3); 446-451.

The authors conducted a clinic-based study of RBC cholinesterase levels, pesticide exposures, and health effects among farmworkers and nonfarmworkers to determine risks for exposure and associated morbidity. Two hundred farmworkers and 42 nonfarmworkers were recruited sequentially at two community health centers. RBC cholinesterase levels were measured colorimetrically. Questionnaires obtained data on demographics, occupational history, exposures and symptoms. Cholinesterase levels were significantly lower among farmworkers (30.28 U/mg hemoglobin) than among nonfarmworkers (32.3 U/mg hemoglobin). Twelve percent of farmworkers, but no nonfarmworkers, had very low levels. Farmworkers applying pesticides also had lower cholinesterase levels. One half of farmworkers reported being sprayed by pesticides and working in fields with an obvious chemical smell. Of reported symptoms, only diarrhea was associated with cholinesterase levels. Reported exposures, however, were strongly associated with symptoms.

16. Stallones L. & Beseler C. (2002). Pesticide Poisoning and Depressive Symptoms among Farm Residents. *Annals of Epidemiology*, vol 12: 389-394.

The purpose of this study was to evaluate the association between exposure to organophosphate compounds and the development of anxiety and depression. Data for this study came from a cross sectional survey of farmers and their spouses conducted in an eight county area in northeastern Colorado. The authors concluded that exposure to organophosphorus pesticides at a high enough concentration to cause self reported poisoning symptoms was associated with high depressive symptoms independently of other known risk factors for depression among farm residents.

## Monitoring for exposure to cholinesterase-inhibiting pesticides

Acetylcholinesterase (AChE) inhibition is considered the primary mechanism of toxicity associated with exposure to organophosphate and N-methyl-carbamate pesticides for reasons that include:<sup>49</sup>

- The character of illness produced is what would be predicted to result from inhibition of AChE and the consequent accumulation of acetylcholine in the tissues.
- The degree and duration of illness are related to the inhibition of AChE.
- Neither the kind nor degree of illness resulting from exposure to cholinesterase-inhibiting pesticides corresponds with the inhibition of other enzymes.
- Illness in experimental animals may be lessened or shortened by providing compounds that prevent phosphorylation or block the action of acetylcholine.

Symptoms of cholinergic poisoning are initially related to functions of the autonomic nervous system and the extent of inhibition of AChE. These symptoms may include slowing of the heart (bradycardia), constriction of the pupil of the eye (miosis), diarrhea, urination, lacrimation, and salivation. Over stimulation of skeletal muscles can cause fasciculations (muscle twitching) and muscle paralysis. Symptoms of central nervous system cholinergic poisoning can include hypothermia, tremors, headache, anxiety, convulsions, coma, and death.<sup>50</sup>

While the toxic mechanism of organophosphate and N-methyl carbamate pesticides is inhibition of AChE in the nervous system it is not practical to measure AChE levels in the peripheral and central nervous systems of humans. Reliable laboratory methods for the measurement of red blood cell and plasma cholinesterase have been available for many years and are the most common methods used for monitoring exposure to cholinesterase-inhibiting pesticides. The EPA has determined that blood cholinesterases are appropriate surrogate measures for nervous system ACHE levels and may be to determine the potential for adverse medical effects.<sup>51</sup>

Three primary types of laboratory assay methods are used to measure blood cholinesterases; these are the electrometric, radiometric and colorimetric methodologies. The radiometric method is least used primarily because of its cost, complexity, and the fact that radioactive waste product is produced from the process. The electrometric method is still used by some laboratories, a primary example being the U.S. Military Cholinesterase Reference Laboratory, which uses a modified Michel method. The most commonly used laboratory testing today is the colorimetric method based on the Ellman assay. California uses an Ellman assay method as its

<sup>49</sup> Gallo MA & Lawryk NJ. Organic phosphorus pesticides. Chapter 16 in the Handbook of Pesticide Toxicology (Hayes & Laws). 1991. San Diego, CA, Academic Press

<sup>50</sup> Wilson B. Chapter 48: The cholinesterases. In the handbook of pesticide toxicology, 2<sup>nd</sup> ed (Kreiger). 2001. San Diego, CA, Academic Press

<sup>51</sup> U.S. Environmental Protection Agency. Use of data on cholinesterase inhibition for risk assessments of organophosphorous and carbamate pesticides. 2000. Office of Pesticide Programs.

standardized laboratory methodology and uses the cholinesterase-testing laboratory at UC Davis to act as a reference laboratory and provide proficiency testing services to its approved laboratories.

Studies have been done to determine the efficacy of using a field test kit to monitor blood cholinesterase levels<sup>52</sup>. There are obvious benefits of being able to monitor workers on-site and provide immediate cholinesterase test results. Unfortunately, all of these studies have identified limitations in the use of field-testing (e.g., temperature control, sample contamination), and none have recommended the use of a field test kit for ongoing monitoring of agricultural pesticide handlers. At present time there is no commercially available test kit that is approved for use outside of the laboratory setting.

Evaluation of exposure to cholinesterase-inhibiting pesticides has also been conducted by measuring metabolites in the urine. Screening for specific metabolites to pesticides used is a sensitive method for detecting exposure. However, there are a few difficulties with using urine metabolite screening in a medical cholinesterase-monitoring program. Groups of pesticides break down into different metabolites requiring that urine sample are screened for multiple metabolites. Metabolites are excreted in the urine very rapidly after exposure, in most cases requiring that urine be collected within 48 hours of exposure. Metabolite screening shows that exposure has occurred but provides little useful information on the physiological impacts of exposure or potential for illness.<sup>53</sup>

Other methods have been used to evaluate for the effects of exposure to cholinesterase inhibiting pesticides. For example, individuals may be examined for the presence of signs or symptoms associated with cholinergic poisoning. These include, but are not limited to, dark field pupil dilation and pinch grip strength testing. While physical measurements of function may be useful in research studies the use of these methods is not helpful to the goal of identifying exposure prior to the onset of illness, thereby providing a means to prevent illness.

After evaluation all of the available evidence L&I has concluded that the standardized Ellman testing method and California's model of approved laboratories coupled with a proficiency testing program is the most appropriate system for a large scale cholinesterase monitoring program. L&I has worked closely with the Washington State Department of Health (DOH) Public Health Laboratory and has instituted a system that will ensure, to the greatest extent possible, the accuracy and consistency of cholinesterase testing services for Washington's cholinesterase-monitoring program.

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<sup>52</sup> Oliveira GH, Henderson JD & Wilson BW. Cholinesterase measurements with an automated kit. American Journal of Industrial Medicine. 2002; suppl.2: 49-53.

<sup>53</sup> Wilson BW, Sanborn JR, O'Malley MA, Henderson JD, & Billitti JR. Monitoring the pesticide exposed worker. Occupation Medicine: state of the art reviews. 1997; (12): 347-363.

## SIGNIFICANT RISK OF WORKER EXPOSURE

L&I has concluded, based on the best available evidence, that pesticide handlers working with covered pesticides face a significant risk of pesticide-related illness. This conclusion is based on consideration of Washington State data, the experience in California, EPA risk assessments, and the judgment that there is substantial under-reporting of pesticide-related illness by agricultural workers.

The pesticides covered by this rule making are recognized as being extremely hazardous. World-wide they are the pesticides most frequently reported in human poisonings. There is no information in the record that suggests exposure to these pesticides does not present a risk of material impairment to pesticide handlers. The precautions and required protections on the pesticide label clearly indicate the risk of poisoning to handlers. The best available evidence indicates that the covered pesticides present a significant risk of illness or injury to pesticide handlers.

It is difficult to identify illnesses resulting from pesticide exposure using traditional methods and it is likely that these methods under-count pesticide-related illnesses. The EPA concluded in its rulemaking related to pesticides that "many incidents of acute and allergic pesticide effects on agricultural workers and pesticide handlers are not diagnosed as such by a physician."<sup>54</sup> In reviewing the data available on the subject in 1992, the EPA made the following observation:

There is considerable uncertainty about the number of such incidents. The available studies which address this issue often suffer from a number of limitations, including reliance on recall of workers that may be affected by the questions asked, samples that are small or that may not be representative, etc. Nonetheless, the Agency believes that, with all their weaknesses with respect to this objective, *existing studies, taken together, are remarkably consistent with a conclusion that undiagnosed cases of pesticide poisoning incidents among the agricultural work force subject to the WPS are likely to be significantly more numerous than those that are diagnosed.*<sup>55</sup>

After discussing the expected benefits of its own rulemaking, the EPA declined to estimate how many such cases were occurring and might be avoided by compliance with the Worker Protection Standard, observing only that "the Agency believes the number is very likely to be large."<sup>56</sup>

These problems in identifying cases of occupational disease have long been recognized as a limitation in using workers compensation, Bureau of Labor Statistics, and other data sources to indicate the extent of such illness.<sup>57</sup> Pesticide poisoning is commonly

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<sup>54</sup> Federal Register, Volume 57, number 163, Friday, August 21, 1992, p. V-17.

<sup>55</sup> *Ibid*, p. V-17, emphasis added.

<sup>56</sup> *Ibid*, p. V-33.

<sup>57</sup> See, for example, Pollack, Earl S. and Deborah Gellerman Keimig, *et al*, *Counting Injuries and Illnesses in the Workplace: Proposals for a Better System*, National Research Council, National Academy Press, 1987, pp. 5, 80-

under-diagnosed and under-reported.<sup>58, 59</sup> Cholinergic poisoning has clinical symptoms that are common to a variety of medical conditions. In general, mild cholinergic poisoning mimics symptoms of the common cold or environmental allergies. A 2001 focus group study conducted by the Washington State Department of Health (DOH) found that 75% of the participating farm workers reported experiencing symptoms of pesticide illness, although it is unknown from the study how many of these were handlers. These included headache, eye irritation, difficulty breathing, and nausea. However, most did not seek medical care for these conditions.<sup>60</sup> These results, now available from DOH in summary form,<sup>61</sup> support the conclusion that a large number of pesticide illnesses in farm workers are never identified.

## Washington Specific Illness Data

One study has investigated cholinesterase depression in pesticide handlers in Washington workplaces. Karr et al.<sup>62</sup> reported significantly depressed cholinesterase values for workers employed in pesticide spray activities in 1993. Ninety-five workers were included in the study and fifty-three of these were involved in spraying pesticides. Nearly all handlers (98%) used tractor-pulled airblast spray equipment. Baseline blood tests were conducted in March and periodic test samples were collected on an approximately monthly interval during June July, and August. For each periodic test approximately 7- 8% of the monitored workers were identified as having test results consistent with significant depression of either plasma or red blood cell cholinesterase. More than 5% (3) of the fifty-three handlers in this study were reported to have test results consistent with significant depression of their red blood cell cholinesterase. These workers reported the use of rain suits, cartridge respirators, and gloves while spraying. "While none reported symptoms suggestive of pesticide over exposure, monitoring results did indicate that these individuals were potentially at greater risk for a symptomatic episode given further exposure."<sup>63</sup>

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100; and *An Interim Report to Congress on Occupational Diseases*, United States Department of Labor, 1980, pp. 1,3

<sup>58</sup> Environmental Protection Agency (1999). Recognition and Management of Pesticide Poisonings, 5th ed. Environmental Protection Agency, Washington D.C.

<sup>59</sup> Washington State Department of Health. Pesticide Incident Report Data. Pesticide Incident Reporting and Tracking Review Panel.

<sup>60</sup> Vanderslice, J., Baum, L., Bardin, J., Bonnar-Prado, J., & Hanks C. (2001). Learning from Listening: Results of Farmworker Focus Groups About Pesticides and Health Care. Washington State Department of Health (unpublished)

<sup>61</sup> Summary Results of Yakima Farmworker Focus Groups about Pesticides and Health Care, Washington State Department of Health, September 22, 2003.

<sup>62</sup> Karr, C., Keifer, M., & Miller M. & Kaufman, J. (1998). Field Based Monitoring of Agricultural Workers for Overexposure to Cholinesterase- inhibiting Pesticides: Evaluation of a Trial Program. Journal of Agromedicine, Vol. 54, pp 35-47.

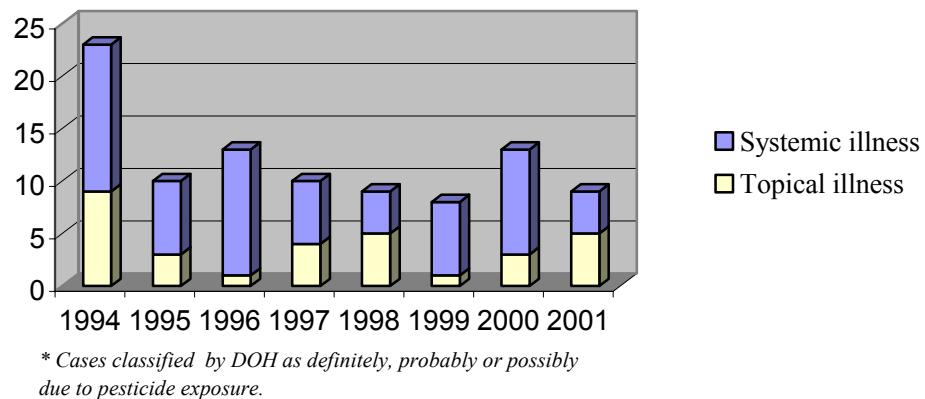
<sup>63</sup> Id.

Another study reported by Simcox et al.<sup>64</sup> documented foliar pesticide residue and urinary metabolites indicating worker were absorbing the residue during apple thinning. While this study does not involve pesticide handlers, it does identify a potential risk to handlers removed from their handling duties due to depressed cholinesterase levels. A removed worker could be assigned thinning duties if this activity was not recognized as having an exposure risk.

Since 1990, the Washington State Department of Health (DOH) has investigated and documented reported cases of pesticide-related illness and injury through a passive surveillance system. The system relies on health care providers to report suspected cases of pesticide-related illnesses and injuries. Most occupation-related cases are not identified until a doctor files a Worker's Compensation Claim with the Department of Labor and Industries (L&I).<sup>65</sup> The Pesticide Incident Reporting and Tracking Review Panel (PIRT) relies primarily on L&I worker's compensation claims data for reporting of incidents of pesticide exposure among workers.

The graph<sup>66</sup> presented below demonstrates that incidents involving exposure to ChE-inhibiting pesticides continue to occur after implementation of Worker Protection Standards, suggesting that cholinesterase monitoring would be a useful tool in further reducing such incidents.

**Systemic and Topical Illness/Injury\* Trend for Agricultural Workers Who Handle AChE Inhibitors Via Mixing, Loading, Applying or Repairing Equipment 1994-2001 (Source: State of Department of Health)**



<sup>64</sup> Simcox NJ, Camp J, Kalman D, Stebbins A, Bellamy G, Lee I, & Fenske R (1999). Farmworker Exposure to Organophosphorus Pesticide Residues During Apple Thinning in Central Washington State. American Industrial Hygiene Association Journal, 60:752-761.

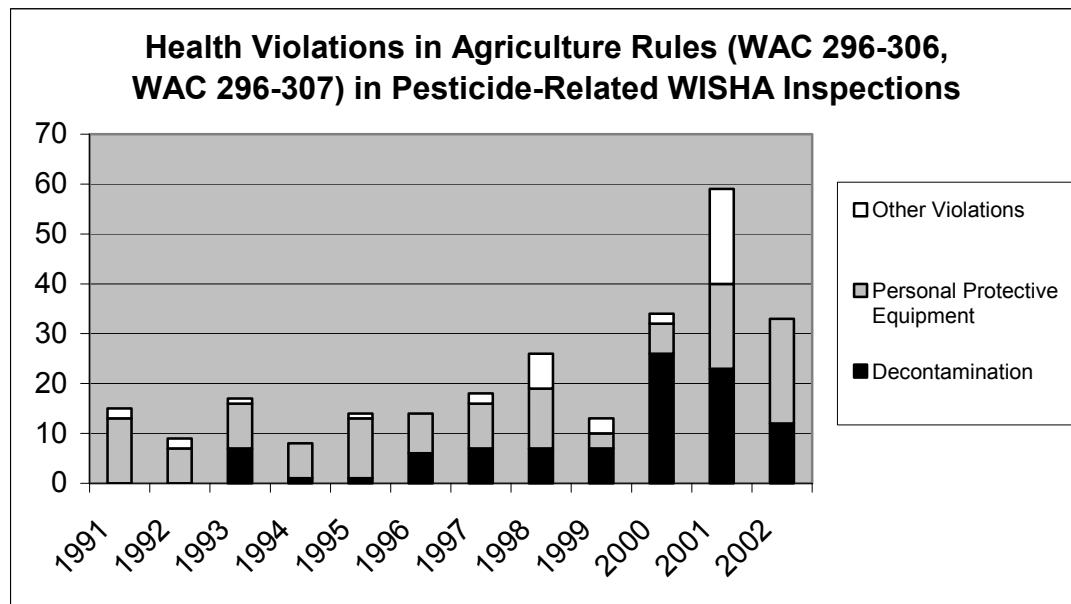
<sup>65</sup> Summary Results of Yakima Farmworker Focus Groups About Pesticides and Health Care, Washington State Department of Health, September 22, 2003.

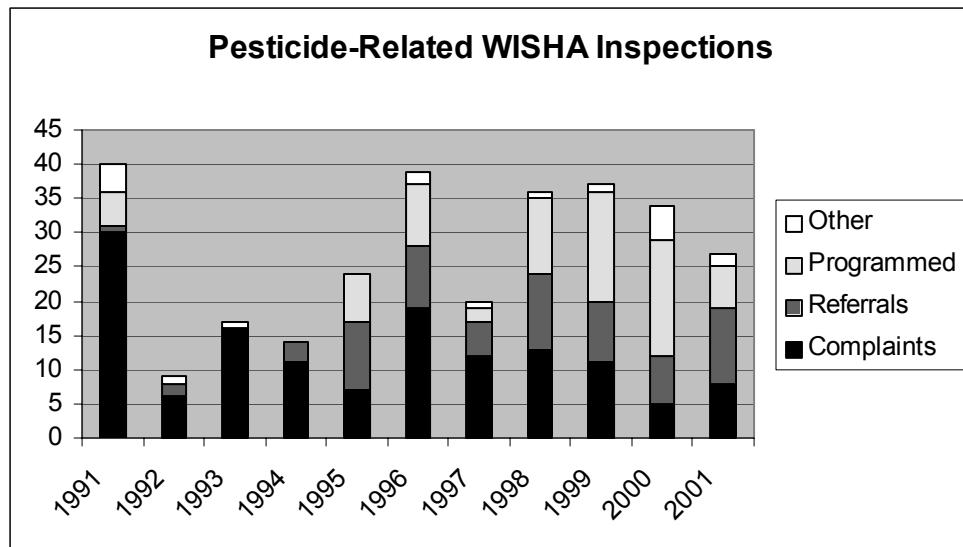
<sup>66</sup> Unpublished 2003 draft, Washington State Department of Health. Pesticide Incident Report Data. Pesticide Incident Reporting and Tracking Review Panel.

Systemic illnesses reported to DOH do not show the downward trend in illness that would be expected given EPA restrictions limiting the use of the most toxic pesticides (such as, phosdrin and parathion) and implementation of the Worker Protection Standard in 1993. This may be due to the relatively small number of “definite” cases of illness included in the PIRT data.

In the context of the present rulemaking, L&I has determined that the PIRT data is useful as an indicator that pesticide use continues to result in over-exposures and illnesses. In light of the recognized under-reporting of pesticide-related symptoms (and occupational illnesses in general), L&I considers the worker’s compensation claims represented by the PIRT data to be an indicator of the overall risk, rather than a quantity representing that risk. While exposures that result in illness and that are correctly linked to pesticide exposures continue to occur, L&I has concluded that a much larger number of unidentified and undiagnosed illnesses also are likely to occur and to go unreported in the absence of a well-designed, comprehensive cholinesterase monitoring program.

The graph below reflects the violations of the Worker Protection Standard (WPS) found as a result of L&I pesticide inspections. Personal protective equipment violations are present in every inspection year, confirming that WPS requirements are not consistently followed in all Washington workplaces. “Other violations” include: posting requirements, pesticide safety training, restricted entry interval, providing specific information about pesticide applications, safe operation of equipment, and labeling. These violations are directly related to an increased risk of handler exposure to covered pesticides.





## California's Cholinesterase Monitoring Program

California has had a cholinesterase-monitoring program in place for agricultural pesticide handlers since 1974.<sup>67</sup> Their program analysis and studies have identified several benefits of routine cholinesterase monitoring.

- Monitoring can identify workers with small but significant ChE depressions, triggering a review of the workers' and employers' safety program to find the source of exposure and make necessary corrections.
- Physicians may remove workers with depressed ChE levels from further exposure, thereby preventing illness.
- Participation in cholinesterase monitoring increases worker and employer awareness of the toxicity of chemicals handled.<sup>68</sup>
- By reducing over-exposure to cholinesterase-inhibiting pesticides, cholinesterase monitoring may protect workers from acute poisoning and from developing possible long-term health effects.<sup>69</sup>

The California cholinesterase monitoring rule is contained in the state's Agricultural regulations.<sup>70</sup> The California Department of Pesticide Regulation (DPR) has primary responsibility for enforcement, along with County Agricultural Commissioners. The Office of Environmental Health Hazard Assessment (OEHHA) has developed a

<sup>67</sup> California Code of Regulations. Title 3 Food and Agriculture, Division 6, Chapter 1 sec. 6728, Medical Supervision.

<sup>68</sup> Ames RG, Brown SK, Mengle DC, Kahn E, Stratton JW, & Jackson RJ. Protecting agricultural applicators from over-exposure to cholinesterase-inhibiting pesticides: perspectives from the California programme. Journal of the Society of Occupational Medicine. 1989; 39: 85-91.

<sup>69</sup> *Ibid.*

<sup>70</sup> California Code of Regulations. Title 3 Food and Agriculture, Division 6, Chapter 1 sec. 6728, Medical Supervision.

guideline manual for physicians on cholinesterase monitoring, which describes medical monitoring from a public health perspective.

Agricultural employers are required to contract with a physician for medical supervision of employees who handle category I and II organophosphate and carbamate pesticides for 6 days or more in a 30-day period. Biannual baselines are required and periodic testing of red blood cell and plasma cholinesterase levels is required on a 30-day basis. After three test intervals at 30 days the testing interval may be extended to 60 days at the discretion of the physician. Medical supervisors are required to use a laboratory approved by the state Department of Health Services to perform cholinesterase testing. Acetylcholine (AChE) depression thresholds for workplace evaluations and medical removal are the same as Washington's adopted rule.

California adopted the requirement to use a standardized Ellman cholinesterase testing method in 1999. The California rule also allows the use of alternative testing methods as long as reporting of cholinesterase test results is referenced to the standardized test method. Laboratories have been required to comply since 2000. Laboratory participation in the cholinesterase-monitoring program has declined since the adoption of a testing standard. In 1996 there were 32 certified laboratories in California that number has declined to 20 certified laboratories in 2003.<sup>71</sup>

The most recent published study of agricultural worker ChE depression done by DPR was the Ames<sup>72</sup> study that analyzed 1985 data and showed a 4.8% worker removal rate using removal thresholds of 40% from baseline for red blood cell cholinesterase and 50% from baseline for plasma cholinesterase. In a 2003 presentation at the Pacific Northwest Pesticide Issues Conference, Dr. Ames presented unpublished data from 1988 and 1989 that analyzed 542 worker records with baseline and midseason test values. This study showed 117 (7.4%) workers had cholinesterase depressions meeting the removal thresholds contained in Washington's adopted rule, of 30% from baseline for red blood cell cholinesterase and 40% from baseline for plasma cholinesterase.

In 1999, OEHHA published the results of a survey of medical supervisors.<sup>73</sup> Out of 101 physicians responding over two-thirds (68.3%) had requested workers to be removed from organophosphate and carbamate exposure due to below-threshold cholinesterase values. The report concluded "that medical supervision program is functioning to protect workers from overexposure to organophosphate and carbamate pesticides."

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<sup>71</sup> Verder-Carlos M. History and state of affairs for cholinesterase monitoring in California. Presentation at the Pacific NW Pesticide Issues Conference. February 2003.

<sup>72</sup> Ames RG, et al. Cholinesterase depression among California agricultural pesticide handlers. American Journal of Industrial Medicine. 1989; 15:143-150.

<sup>73</sup> California Environmental Protection Agency. Results of a survey regarding certification and training for physicians providing medical supervision for California pesticide mixer/loader/applicators. Office of Environmental Health Assessment . 1999.

The following references summarize the findings of studies of exposure to organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides in California and the California cholinesterase monitoring program:

1. Fillmore CM & Lessenger JE. (1993). A Cholinesterase Testing Program for Pesticide Applicators. *Journal of Occupational Medicine*; (35)1: 61-70.

In this California retrospective cohort study 103 worker years of cholinesterase-monitoring are reported. Twenty-four (24%) of workers were temporarily removed from spraying (five were removed twice) because their cholinesterase plasma activity levels were below 60% of baseline. Five workers (5%) had mild symptoms of toxicity but none reported a specific incident of exposure.

2. Ames RG & Menendez RE. (1999). Results of a Survey regarding Certification and Training for Physicians Providing Medical Supervision for California Pesticide Mixer/Loader/Applicators. California Environmental Protection Agency.

Data from this survey support the premise that the medical supervision program is functioning to protect workers from overexposure to organophosphate and carbamate pesticides; over two-thirds (68.3%) of the supervisors had requested employees to be removed from organophosphate or carbamate exposure due to below-threshold cholinesterase values.

3. Brown SK, Ames RG, & Mengle DC (1989). Occupational Illnesses from Cholinesterase-Inhibiting Pesticides among Agricultural Applicators in California, 1982-1985. *Archives of Environmental Health*; (44) 1: 34-39.

California pesticide illness investigating reports involving toxicity category I and II organophosphate and carbamate pesticide exposures among agricultural pesticide applicators were reviewed for the years 1982-1985. The pesticides associated with each illness were recorded, and the exposures were classified as chronic, short-term, or accidental. Illnesses were associated with a range of pesticides, including both organophosphates and carbamates in both toxicity categories I and II. Approximately 19% of the illnesses were due to accidents. Overall, the analysis identified a need for improving occupational health surveillance and the regulations governing worker health and safety.

4. Ames RG, Brown SK, Mengle DC, Kahn E, Stratton JW, & Jackson RJ (1989). Cholinesterase Activity Depression among California Agricultural Pesticide Applicators. *American Journal Of Industrial Medicine*; 14: 143-150.

Cholinesterase activity measurements for 542 California agricultural pesticide applicators under medical supervision during the first 9 months of 1985 were

analyzed. Twenty-six workers, 4.8% of the sample, had cholinesterase values at or below the California threshold values for removal from continued exposure to cholinesterase-inhibiting pesticides (60% of baseline for red blood cell cholinesterase and 50% of baseline for plasma cholinesterase. Eight of these 26 workers, 31.5%, had pesticide-related illness.

5. Ames RG (2003). Unpublished study presented at the Pacific Northwest Pesticide Health and Safety Conference.

Data call-ins in 1988 and 1989 were used to examine the effects of changes to the California cholinesterase monitoring regulation that took effect in 1989. Using the 1989 threshold values of 30% decrease in RBC cholinesterase from baseline and 40% decrease in plasma cholinesterase from baseline, 117 workers (7.4% of population) had depression below the exposure removal threshold.

## **Under-reporting of Pesticide Illnesses**

Under-reporting of occupational illness has been a recognized problem for many years. In 1968 California reported “Low earnings, short term opportunity for work, migrant status, frequent lack of accessible medical care facilities, language barriers and ignorance of their rights under Workmen’s Compensation, are a few of the factors that predispose farm workers to neglect seeking medical care altogether or to secure such care outside the Workmen’s Compensation system at their own expense.”<sup>74</sup> In the Regulatory Impact Analysis<sup>75</sup> for the 1992 Worker Protection Standard, EPA identified several factors that contribute to a pesticide related illness not being reported.

1. Workers must perceive that they have treatable symptoms.
2. Workers must seek medical attention.
3. The physician must diagnose symptoms as being pesticide related.
4. The incident must be reported to the correct recordkeeping system and be recorded as pesticide-related.

Azaroff et al. described a detailed model to explain the under-reporting of occupational illnesses.<sup>76</sup> Reporting health problems to supervisors may subject workers to “disciplinary action, denial of overtime or promotion opportunities, stigmatization, drug testing, harassment, or job loss.”<sup>77</sup> “Workers with insecure job status, limited permission to work, or lack of marketable job skills are particularly vulnerable to the dangers of reporting. Low-wage and immigrant workers are especially likely to be fired or threatened for complaining.”<sup>78</sup>

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<sup>74</sup> Occupational Disease in California Attributed to Pesticides and Other Agricultural Chemicals, State of California Department of Public Health, Bureau of Occupational Health and Environmental Epidemiology, 1968

<sup>75</sup> Regulatory Impact Analysis of Worker Protection Standard for Agricultural Pesticides; U.S. Environmental Protection Agency, Office of Pesticide Programs, Biological and Economic Analysis Division, pg. V-11

<sup>76</sup> Azaroff, L., et al; Occupational Injury and Illness Surveillance: Conceptual Filters Explain Underreporting; American Journal of Public Health; September 2002, Vol. 92, No. 9, pg. 1421-1429

<sup>77</sup> Id.

<sup>78</sup> Id.

If pesticide handlers do not access the available medical care when they have a pesticide-related illness, the current systems for tracking pesticide illness cannot account for them. The Washington State department of Health has reported that the use of medical care by farmworkers is affected by a number of factors, including:<sup>79</sup>

- Economic
  - Cannot afford the loss of wages.
  - Fear of job loss.
  - Cannot afford to pay for office visits or prescriptions.
- Undocumented workers are much less likely to seek medical attention for fear of being deported
- The belief that doctors did not properly diagnose pesticide-related illness because the doctors, in essence, work for the employers.
- Health care providers do not seriously consider pesticide exposure as the cause of their condition.
- The attitude of a supervisor or employer could be a barrier to seeking medical care.
- Some other factors that were identified:
  - The belief that they would feel better with time.
  - Paperwork.
  - Long waits in clinics.
  - Lack of transportation

## EPA and the Worker Protection Standard

EPA promulgated the Worker Protection Standard (WPS) in 1992 and it became fully effective in 1995. The EPA rule was incorporated into the regulations of the Washington State departments of Agriculture and Labor and Industries, the Washington legislature having mandated that the two agencies coordinate rulemaking for agricultural workers and handlers of agricultural pesticides.<sup>80</sup>

EPA, drawing on its expertise in regulating pesticides, determined that the simple measures in the WPS were likely to reduce substantially the number of pesticide-related illnesses and injuries to agricultural employees. Both the frequency of illness and injury incidents under existing conditions and the expected reduction in the number and severity of these incidents due to promulgation of the WPS are difficult to quantify. However, the EPA believed that the reductions would be significant.<sup>81</sup> In the Regulatory Impact Analysis for the WPS, EPA estimated that protections from the WPS for pesticide handlers “.... may have an efficacy rate of only about 80 percent.” reflected as

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<sup>79</sup> *Summary Results of Yakima Farmworker Focus Groups about Pesticides and Health Care*, Washington State Department of Health, September 22, 2003.

<sup>80</sup> RCW 49.17.280

<sup>81</sup> Federal Register, Volume 57, number 163, Friday, August 21, 1992

a reduction in the incidence of the adverse health effects from pesticide exposures.<sup>82</sup> Based on the incidents reported by the Washington State Department of Health in the PIRT reports, a reduction in the incidence of pesticide illness, resulting from implementation of the WPS, has not been documented.

In this rulemaking, L&I has considered the record in light of the WPS requirements, and in light of the EPA's own assessments of those requirements' practical effectiveness. EPA's risk assessments conclude that pesticide handlers "are subject to significant levels of exposure" even when appropriate protective equipment is worn and engineering controls are used.<sup>83 84</sup>

EPA has conducted risk assessments for many covered pesticides<sup>85, 86, 87, 88</sup>. These assessments are used to quantify the risk to various segments of the population and to pesticide handlers, to specify pesticide use restrictions and protections, and to reevaluate the approved uses of a pesticide. EPA is charged with protection of the public, including children, and this necessitates that their risk assessments consider factors beyond the scope of worker protection. From their risk assessments EPA concludes there is a risk to handlers and workers from organophosphate and N-methyl-carbamate pesticides that requires risk mitigation measures such as those below.

The EPA assessment of risk for organophosphate and N-methyl-carbamate pesticides can be summarized as indicating that many exposures to handlers can be controlled by properly worn PPE and properly used engineering controls; however, worker exposures will exceed acceptable levels under certain conditions, even with the use of maximum PPE or engineering controls.

Reregistration Eligibility Decisions (RED) for organophosphate and N-methyl-carbamate pesticides include analysis of the WPS protections for pesticide handlers. Some information from pesticides widely used in Washington (azinphos-methyl, phosmet, and chlorpyrifos)<sup>89, 90, 91, 92, 93</sup> are included here to provide an example of the extent of the

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<sup>82</sup> Regulatory Impact Analysis of Worker Protection Standard for Agricultural Pesticides; U.S. Environmental Protection Agency, Office of Pesticide Programs, Biological and Economic Analysis Division, pg. V-31

<sup>83</sup> Revised Occupational Handler Exposure Assessment and Recommendations for the Registration Eligibility Decision Document for Azinphos Methyl, July 10, 2001

<sup>84</sup> Agricultural and Occupational Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Chlorpyrifos, October 6, 1999

<sup>85</sup> The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides, Internal Deliberative Draft, March 22, 2000

<sup>86</sup> Agricultural and Occupational Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Chlorpyrifos, October 6, 1999

<sup>87</sup> Interim Registration Eligibility Decision for Azinphos-methyl, October 30, 2001

<sup>88</sup> Revised OP Cumulative Risk Assessment, part 1, June 11, 2002

<sup>89</sup> Memorandum of Agreement between the Environmental Protection Agency and the Registrants of Pesticide Products Containing Azinphos Methyl, May 23, 2002

<sup>90</sup> Memorandum to docket number 34131D explaining revisions to Appendix D of the azinphos-methyl Memorandum of Agreement, dated May 23, 2002

<sup>91</sup> EPA : Clorpyrifos Facts, February 2002

<sup>92</sup> EPA : Azinphos-Methyl IRED Facts, October 31, 2001

<sup>93</sup> EPA : Phosmet IRED Facts, October 31, 2001

analysis and changes implemented by EPA through the reregistration process. EPA and the registrants have agreed to certain registration changes specifically to reduce exposure risks to field workers and handlers. Examples of the types of changes implemented on a case-by-base basis for organophosphate and N-methyl-carbamate pesticides include:

- Cancel crop uses where safer pest control alternatives are available
- Phase out crop uses over 4 years, allowing time to shift to safer pest control alternatives
- Issue time-limited registrations, allowing for development of safer pest control alternatives
- Cancel all liquid products
- Cancel use of hand held equipment
- Increase restricted entry intervals
- Increase preharvest interval
- Require closed transfer systems
- Require enclosed cabs or maximum personal protective equipment (PPE) for applicators
- Limit application frequency and amount
- Conduct studies and provide data
  - Comparing exposure to airblast applicators with enclosed cabs, chemical resistant suits, or other PPE;
  - Monitoring cholinesterase levels of field workers; and
  - Glove feasibility.

EPA, WSDA and L&I enforce WPS and label requirements; however, the risk to field workers and handlers from organophosphate and N-methyl-carbamate pesticides has not been effectively quantified. Indeed, the effectiveness of the WPS requirements for covered pesticides will not be fully realized, and certainly cannot be evaluated, in the absence of a well-designed, comprehensive medical-monitoring and data collection program.

The presumption of the WPS is that the effective use of PPE and engineering controls will protect workers from pesticide-related illness. L&I mandates the use of engineering controls or PPE. In many instances engineering control are required<sup>94</sup> because they are considered more reliable and effective than PPE in controlling employee exposure; however, these controls require maintenance and may be subject to failure. The most basic breakdown of the EPA risk assessments regarding PPE and engineering controls is the failure of pesticide handlers to use the required PPE or engineering controls. Comments from stakeholders (both supporters and opponents of the rule) confirm the importance of enforcing the use of required PPE (and engineering controls) among the workforce in order to avoid poisoning. Even when PPE and engineering controls are used properly there is a question of their effectiveness in protecting handlers from

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<sup>94</sup> chapter 296-62 WAC

excessive exposure. As noted above, the EPA's own analysis<sup>95</sup> estimated no more than 80 percent effectiveness from the precautions, PPE, and engineering controls required by the WPS and label. L&I requires medical monitoring, in addition to engineering and administrative controls and PPE that L&I expects to be effective with optimum usage, to ensure the protection of employees from workplace hazards such as, benzene, formaldehyde, and lead.<sup>96, 97, 98</sup>

In determining whether a state requirement for a medical monitoring program is necessary supplement to the WPS requirements, L&I recognizes that such monitoring is designed to work in tandem with other requirements, such as those included in the WPS. Medical monitoring allows employers, employees and regulatory agencies to assess effective implementation of work practice, personal protective equipment, and engineering control requirements, such as those mandated under the WPS. In addition, it allows the effectiveness of the requirements themselves to be evaluated for adequacy when appropriate data collection and analysis is included.

The WISHAct<sup>99</sup> also provides for medical monitoring of workers to most effectively determine whether the health of workers is adversely affected by exposure to covered pesticides. Although in the present case L&I has determined that a significant risk exists, legal standards would allow L&I to impose monitoring and medical surveillance even if it is unsure that a significant risk exists, to check the validity of its assumptions, or to develop evidence for a revised standard, or to protect susceptible workers from harm.<sup>100</sup>

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<sup>95</sup> Regulatory Impact Analysis of Worker Protection Standard for Agricultural Pesticides; U.S. Environmental Protection Agency, Office of Pesticide Programs, Biological and Economic Analysis Division, pg. V-31

<sup>96</sup> WAC 296-62-07523, Benzene

<sup>97</sup> WAC 296-62-07540, Formaldehyde

<sup>98</sup> WAC 296-62-07521, Lead

<sup>99</sup> RCW 49.17.240(2)

<sup>100</sup> National Cottonseed Prods. V. Brock, 825 F.2d 482, 485, 13 OSH Cases 1353 (D.C. Cir. 1987)

## **THE RULE IS TECHNOLOGICALLY AND ECONOMICALLY FEASIBLE FOR AFFECTED INDUSTRIES**

### **Summary of small business economic impact study (RCW 19.85)**

Overall, the SBEIS concluded that the recordkeeping requirements of the rule would apply to an estimated 4800 handlers employed by 1700 businesses. The rule will require these businesses to offer medical monitoring to an estimated 1100 pesticide handlers in the first year and an estimated 3000 handlers per year beginning in the second year. The department estimated a total cost of just over \$925 thousand for the first year and just over \$2 million beginning in the second year.

To examine possible disproportionate impacts on small businesses affected by the proposed rule, L&I analyzed the rule's effect on employers *who used the covered pesticides* in three categories, identified using Standard Industrial Classifications (SIC): Professional applicators (SIC 0721); orchardists (SIC 0175); and other growers (SIC 0111, 0115, 0119, 0134, 0139, 0161, 0171, 0172, 0811). In each case, L&I relied upon data from an employer survey and other available information to develop the most likely cost estimate, located centrally within a range of possible costs.

L&I then compared the estimated costs to small employers with the costs to the largest 10 percent of employers within each industry sector to identify any disproportionate economic impacts.<sup>101</sup>

Table 1 summarizes the findings of the Small Business Economic Impact Statement

**Table 1: Central Cost Estimates by Industry Sector**

	Per Firm	First Year		Second Year	
		Per Handler	Per Firm	Per Handler	Per Firm
<b>Professional Applicators</b>					
Small Business	\$892	\$517	\$1218	\$706	
Largest 10 Percent	\$4532	\$504	\$5511	\$612	
Small +/- Larger		+2.6%		+15.4%	
<b>Orchardists</b>					
Small Business	\$346	\$169	\$956	\$466	
Largest 10 Percent	\$1786	\$205	\$4034	\$463	
Small +/- Larger		-17.6%		+0.6%	
<b>Other Growers</b>					
Small Business	\$217	\$165	\$315	\$239	
Largest 10 Percent	\$553	\$144	\$1023	\$267	
Small +/- Larger		+14.6%		-10.5%	

<sup>101</sup> In each industry sector, some small businesses also fell within the largest 10 percent. In those cases, the business was excluded from the small employer group in order to avoid distorting the comparison by including the same business in both samples.

Based on this analysis, L&I concluded that there would be a disproportionate impact on small business in the professional applicator sector, beginning in the second year. In the Other Growers sector, there is a disproportionate impact in the first year alone, apparently because of a relatively small distribution of small businesses that are moderate users of the covered pesticides. However, from the second year forward, the relative impact is greater on large businesses in the Other Growers sector. In Orchards, there does not appear to be a large enough variation between large and small growers to describe it as a disproportionate impact.

Because L&I recognized the possibility of a disproportionate impact in one or more sectors, the rule contains several mitigations to reduce the impact of the rule on small businesses without compromising worker protection. In addition to the mitigations reflected by the rule itself, L&I will take additional steps to further mitigate the impacts. Both sets of mitigations are outlined in the “Rule Implementation Plan” section.

## **Summary of Benefit-Cost Determination (RCW 34.05.325)**

Although the compliance costs of the rule can be estimated in quantitative terms with some degree of confidence, the benefits are less susceptible to such quantitative analysis.

L&I has identified a range of benefits, primary among them being the protection of worker health and prevention of serious illness, as well as the increased knowledge and more reliable information that the monitoring and recordkeeping provisions of the rule would themselves generate. L&I has then balanced these benefits against the costs of the rule, which the final analysis has concluded will be roughly \$860 thousand in the first year and \$1.3 million per year beginning in the second year.

After considering the statutory mandates of the Washington Industrial Safety and Health Act (WISHA), the guidance provided by the state Supreme Court in the *Rios et al v. Washington Department of Labor and Industries et al* decision that prompted the rulemaking, and the best available evidence upon which the benefits of the rule are based, L&I has concluded that the benefits of the rule outweigh its costs. The full analysis found in the Benefit-Cost Determination (BCD) also reflects an analysis of a “low cost” and “high cost” scenario. In both cases, L&I confirmed the determination that the probable benefits of the rule outweigh its probable costs.

## **Summary of Evidence for Technological Feasibility**

The relationship between cholinesterase depression caused by exposure to organophosphate and N-methyl-carbamate pesticides and cholinergic poisoning is well established. Blood cholinesterase assays provide the most accurate and practical means to measure a physiologic reaction that indicates exposure to these pesticides and an increased potential for pesticide-related illness.

Laboratory blood assays have been used to measure blood cholinesterase levels for over 50 years. They offer the advantages of specificity, simplicity, rapidity, automation,

relative noninvasiveness, and low expense.<sup>102</sup> The primary benefit from measuring cholinesterase activity is that significant depressions in cholinesterase levels can be clearly and accurately identified and employees can then be removed from further exposure before illness occurs.

The most commonly used assay is one based on the Ellman assay method. This is a relatively simple assay method that is easily automated, inexpensive, and can be performed using whole blood. This eliminates the need to centrifuge sample prior to storage or shipping. It is important that blood samples be stored at 2-4 degrees centigrade; however, keeping blood samples cold is required with many laboratory test procedures and is a common practice in laboratories and medical offices. The provision of specific procedures for collection, storage, and transport of specimens by the laboratory performing the analysis will minimize collection and handling errors.

The major technologic difficulties identified in a large-scale cholinesterase-monitoring program are the use of different laboratories, laboratory methodologies, and difficulty in comparing test results reported in different units. California recently implemented a standardized testing protocol when it discovered wide variations in test results reported from different laboratories.<sup>103</sup> L&I has addressed the issue of laboratory variability by requiring the use of the Washington State Department of Health Public Health Laboratory (PHL) for all tests conducted in 2004 and 2005. The PHL will be using a standardized Ellman assay method, provide standardized collection, storage, and transporting procedures, and work closely with medical providers and L&I. In 2006 any laboratory approved by L&I and using the laboratory assay method developed by the PHL will be able to provide cholinesterase testing for Washington's agricultural employers.

In addition, to ensure accuracy and consistency of laboratory testing the PHL is working closely with the cholinesterase-monitoring laboratory at UC Davis, California. The PHL will participate in the UC Davis cholinesterase testing proficiency program. Once the PHL program is established it can become the cholinesterase testing reference laboratory for Washington State and provide proficiency testing services to other laboratories approved in 2006.

Medical professionals are available to growers, in all areas of the state, to perform the medical services needed for an effective cholinesterase monitoring program. L&I has compiled a preliminary list of medical services available in areas of the state with high usage of the covered pesticides. Usage of the covered pesticides currently requires a medical evaluation for respirator use, so it is presumed that growers already have a relationship with a medical service provider in their area.

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<sup>102</sup> Wilson BW, Sanborn JR, O'Malley MA, Henderson JD, & Billitti JR. Monitoring the pesticide-exposed worker. 1997; (12(2): 347-363.

<sup>103</sup> Verder-Carolos M. History and state of affairs for cholinesterase monitoring in California. Presentation: Pacific NW Pesticide Safety Conference. 2003

The factors affecting farmworker reporting of pesticide-related illnesses, discussed in the body of this CES, are not relevant to farmworker use of medical services for cholinesterase testing. Cholinesterase testing is employer provided and all cost is borne by the employer. The employer's providing of the medical monitoring program eliminates the barriers of transportation, time away from work (pay), discrimination, and access to services.

## Summary of Evidence for Economic Feasibility

L&I concluded that the evidence in the record, while highlighting the competitive pressures from other states and countries, supports the economic feasibility of cholinesterase monitoring.

The strongest evidence for the economic feasibility of cholinesterase monitoring for pesticide handlers is the experience of the State of California where cholinesterase monitoring has been required since 1974 and has not threatened the viability of agricultural employers. There is no evidence in the record indicating that the California regulation for cholinesterase monitoring is not economically feasible or that the regulation has jeopardized the existence of the affected sectors of California agriculture.

L&I has estimated the compliance costs of the rule to be roughly \$860 thousand in the first year and \$1.3 million per year beginning in the second year.<sup>104</sup> Table 1 includes this central estimate, as well as the high and low estimates for the same period.

**Table 1: Estimated Compliance Costs**

	<b>Central</b>	<b>High</b>	<b>Low</b>
<b>First Year</b>	\$858,490	\$1,159,349	\$688,668
<b>Second Year</b>	\$1,274,487	\$1,730,364	\$1,096,165

The medical test for cholinesterase will be generally available in Washington through medical professionals and laboratories approved by L&I. L&I will mitigate laboratory and medical costs of the cholinesterase monitoring program during the first year to the extent possible using a \$378,000 legislative appropriation; however, this funding is not reflected in table 1.

The SBEIS and BCD have estimated costs to the agricultural sector for a cholinesterase monitoring program. These estimates are a reasonable assessment of the costs agricultural employer will incur to comply with the cholinesterase monitoring rule. L&I has concluded that compliance with the rule does not threaten the financial health and profitability of the affected sectors of Washington's agricultural industry.

<sup>104</sup> BENEFIT-COST DETERMINATION: CHOLINESTERASE MONITORING IN AGRICULTURE, WAC 296-307-148, WASHINGTON STATE DEPARTMENT OF LABOR AND INDUSTRIES

## SUMMARY AND EXPLANATION OF THE RULE

### Chronology of rule development

L&I began the rule development process April 30, 2002, at the direction of the Washington State Supreme Court following a successful lawsuit by farm workers who were exposed to the hazard posed by organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides. See Rios v. Dep't of Labor and Indus., 145 Wn.2d 483, 39 P3.d 961 (2002).

Before drafting the proposed rule, L&I actively engaged the business, labor and health professional communities in detailed discussions. These discussions included seven public information-gathering sessions around the state in July 2002, which were followed by several stakeholder meetings.

After the proposed rule was issued there were eight formal public hearings in eight cities around the state. Eighty-five witnesses testified. L&I received more than twenty public and post-hearing comments. In addition, L&I reopened the comment period to receive comments specifically on the Benefit Cost Determination (BCD). L&I received more than eight written comments on the BCD.

We need the actual number of people that submitted comments, not the number of comments.

### Explanation of the rule

The final rule includes the following provisions:

1. The employer will be required to keep records of all employee handling of covered pesticides, and retain those records for seven years.
2. Cholinesterase monitoring (RBC and plasma cholinesterase) will be required for employees who handle covered pesticides for 50 or more hours in any consecutive 30-day period beginning February 1, 2004, and for 30 or more hours in any consecutive 30 day period beginning February 1, 2005.
3. Employers will be required to ensure that employees requiring medical monitoring will receive training that includes at a minimum:
  - The human health hazards associated with exposure to organophosphate and N-methyl-carbamate pesticides
  - The purpose and requirements of cholinesterase monitoring.
4. Employers will identify a medical provider to provide (at no cost to the employee, and at a reasonable time and place) baseline and periodic testing, interpretation of test results, and recommendations resulting from those test results
5. Employees may choose to decline cholinesterase testing after receiving training and consulting with the medical provider.

6. Pre-exposure baseline testing will be conducted annually.
7. Employers with employees who handle only N-methyl-carbamate pesticides will be exempt from the requirement to offer those employees cholinesterase testing.
8. Hours spent mixing and loading using closed systems (as described in WAC 296-307-13045(4)(d)) will not be counted as exposure hours for the purposes of periodic testing.
9. Periodic testing will be required within 3 days of meeting the designated exposure thresholds or at least every 30 days while exposure is expected to exceed thresholds.
10. Cholinesterase depressions will require the following employer actions:
  - A depression of more than 20% from the employee's personal baseline will require the employer to conduct a work practice evaluation.
  - An RBC cholinesterase depression of 30% or more from the personal baseline or a plasma cholinesterase depression of 40% or more from the personal baseline will require the employee to be temporarily removed from organophosphate and N-methyl-carbamate exposure and the employer to conduct a work practice evaluation.
  - An employee removed from exposure will not be allowed to return to handling of covered pesticides or participate in other activities with exposure until his or her cholinesterase levels are within 20 percent of the personal baseline.
11. Medical removal protection will be made available to employees removed from handling due to cholinesterase depression, until the employee is able to return to normal duties (not to exceed 3 months).
12. The employer must provide for the maintenance of testing and related medical records for 7 years.
13. The exposure thresholds in the rule will be evaluated by L&I (in consultation with both a scientific panel and a stakeholder advisory group) before the 30-hour threshold takes effect and again before the third year of the rule's existence. L&I will propose changes to the rule if appropriate based on these evaluations.

## **Reasons for adopting the rule**

L&I has decided to adopt the cholinesterase monitoring rule based on the following reasons:

1. Exposure to cholinesterase-inhibiting pesticides presents a significant risk of serious health effects.
2. The rule will enable employers, employees, L&I and other agencies to assess both the adequacy of and compliance with existing personal protective equipment, work practice and engineering control requirements found in the pesticide Worker Protection Standard.
3. Measurement of red blood cell and plasma cholinesterase's activity levels are appropriate surrogates for nervous system acetylcholinesterase activity.

4. Cholinesterase blood testing is both economically and technologically feasible.
5. Detection of depressed blood cholinesterase levels and removal of the worker from further exposure has shown to be effective in preventing illness.
6. Data from the Environmental Protection Agency, California Department of Pesticide Regulation, Washington State Department of Labor & Industries, and Department of Health Pesticide Program indicate that the requirement to use label precautions, engineering controls and personal protective equipment is not adequate to prevent pesticide-related illness in agricultural pesticide handlers.

The rule will serve to resolve uncertainty about the extent of exposure to cholinesterase-inhibiting pesticides and correct any current inequities in compensation to employees for illnesses associated with occupational exposure to these pesticides.

## **APPENDIX C: ADDITIONAL REQUIREMENTS OF THE ADMINISTRATIVE PROCEDURE ACT AND THE WASHINGTON SAFETY AND HEALTH ACT**

### **Analysis of alternatives to rulemaking (RCW 34.05.328(1b))**

L&I considered three primary non-rulemaking alternatives.

- Continuing voluntary cholinesterase monitoring, including increased technical assistance to employers and increased educational efforts;
- Increased enforcement of existing regulations and clearer enforcement policies;
- Relying upon EPA/WSDA regulation and pesticide registration changes

#### **Continuing voluntary efforts**

The department has had a voluntary cholinesterase monitoring rule since 1993. L&I has staff available to provide information and technical assistance to employers to help control pesticide hazards. During this time period, private companies, consultants, safety and health professionals, labor unions, and others have also encouraged and assisted employers. Despite these efforts, farm worker representatives felt these practices were insufficient and, as a result, filed a petition for rulemaking that requested L&I make cholinesterase monitoring mandatory. L&I's denial of this petition led to the challenge that resulted in the *Rios* decision, discussed above. The Washington Supreme Court agreed that denial of the request for rulemaking was arbitrary and capricious and ordered L&I to initiate this rulemaking on mandatory cholinesterase monitoring. Based on evidence in the record L&I has concluded that continued use of the voluntary cholinesterase monitoring rule is insufficient to address the significant risk to pesticide handlers associated with the use of covered pesticides.

The DOH pesticide program report on agricultural illness to handlers from cholinesterase inhibiting from 1997 through 2001 is summarized in the table below. It is difficult to draw conclusions regarding the effectiveness of voluntary monitoring programs from this and other PIRT data. Also, only a few growers indicated they had tested employees with a voluntary cholinesterase-monitoring program.

**Illness Type\* for Agricultural Mixer/Loader/Applicator/Equipment Maintenance Workers\*\* by Cholinesterase Inhibiting Pesticides 1997 – 2001 \*\*\*<sup>105</sup>**

Pesticide	1997		1998		1999		2000		2001		Totals	
	Sys	Top	Sys	Top								
Azinphos methyl		1	2				1	1			3	2
Chlorpyrifos			1				2				3	
Diazinon	1										1	
Dimethoate									1		1	
Phorate					1						1	
Combinations of AChE inhibitors with other products	6	3	1	5	6	1	7	2	4	4	24	15
Totals	7	4	4	5	7	1	10	3	5	4	33	17

\*Type of illness/injury: Sys = Systemic: Any health effects not limited to the skin and/or eye.

Top = Topical: health effects involving only the eyes and/or skin.

\*\*Limited to cases with illness classified by DOH as definitely, probably or possibly due to pesticide exposure.

\*\*\*State of Washington Department of Health

## Using existing rules

The Washington State Supreme Court determined that relying on existing regulations to address pesticide hazards would be an unacceptable alternative to initiating rule making. Existing rules, such as Pesticides (Worker Protection Standard) (WAC 296-307 part I) and Respiratory Protection (WAC 296-62 part E), do establish an obligation for employers to address recognized hazards that can cause pesticide poisoning. These regulations have been used as the basis for WISHA inspections and consultation visits in the past. However, these regulations do not provide employers, employees or L&I staff with the means to evaluate the effectiveness of control measures and PPE in protecting employees from exposures to organophosphate and N-methyl-carbamate pesticides. While these rules affirmatively require employers to take specified “protective” actions to address hazards, they are insufficient to ensure effective monitoring and elimination of employee exposure.

Because these rules do not provide employers a means to verify effective implementation they have not been acceptable tools for ensuring equal protection for all employees at risk for poisoning from covered pesticides. L&I believes that a cholinesterase-monitoring rule will provide more uniform employee protection and more equitable employer impact.

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<sup>105</sup> Figure 10 from the Draft 2003 Annual Pesticide Incident Reporting and Tracking (PIRT) Review Panel Report.

## Relying on EPA/WSDA regulation

Another alternative to rule making is relying on federal EPA and the Washington State Department of Agriculture to control hazardous employee exposure to organophosphate and N-methyl-carbamate pesticides through the pesticide registration process. This alternative was rejected for three reasons. First, WISHA has the opportunity to fashion a rule that reflects the input of Washington State employers and employees and takes into account specific features of the state's crops, growing seasons, pesticide usage, and industry demographics. Second, waiting for EPA/WSDA is unpredictable. EPA is currently involved in an assessment of the WPS and has invested several years in reregistering pesticides. The reregistration effort has produced significant changes aimed at reducing the risk to pesticide handlers; however, some changes are being phased in over several years and EPA has acknowledged the remaining risk to pesticide handlers is significant.<sup>106, 107, 108</sup> Waiting involves a significant risk that additional Washington workers will suffer pesticide poisoning that could be prevented by this rule. Third, WISHA has responsibility for worker safety and health and cannot defer that responsibility to a third party, even a federal or state agency. Furthermore, EPA acknowledges that compliance is a continuing problem and, even in the event of full compliance with their regulations, pesticide handlers will be exposed to an unacceptable level of risk from organophosphate and N-methyl-carbamate pesticides. WISHA must perform an assessment of the need for a regulation that includes evaluating the input and actions of other regulatory agencies.

## Determination that the final rule is the least burdensome alternative for those required to comply that will achieve the general goals and specific statutory objectives (RCW 34.05.328(1d))

L&I considered the following non-rulemaking alternatives to the final rule:

- Continuing voluntary cholinesterase monitoring, including increased technical assistance to employers and increased educational efforts;
- Increased enforcement of existing regulations and with clearer enforcement policies;
- Relying upon EPA/WSDA regulation and pesticide registration changes.

As described above, the non-rulemaking alternatives were rejected because L&I concluded they would not achieve the general goals and specific objectives of the Washington Industrial and Safety and Health Act. It is not necessary, therefore, to determine whether they would be less burdensome ways to achieve the general goals and objectives.

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<sup>106</sup> Revised Occupational Handler Exposure Assessment and Recommendations for the Registration Eligibility Decision Document for Azinphos Methyl, July 10, 2001

<sup>107</sup> Agricultural and Occupational Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Chlorpyrifos, October 6, 1999

<sup>108</sup> Memorandum of Agreement between the Environmental Protection Agency and the Registrants of Pesticide Products Containing Azinphos Methyl, May 23, 2002

L&I considered the following rulemaking alternatives in developing the final rule:

- A rule with a single threshold of 30 hours exposure
- A rule requiring baseline testing and additional testing triggered by an exposure incident
- A rule also covering non-agricultural pesticide handlers
- Excluding medical removal protection from the rule
- A rule exempting small businesses
- A rule limited to commercial applicators

These rulemaking alternatives were rejected because L&I concluded they would be significantly less effective than the final rule or unduly burdensome. A rule with a single threshold of 30 hours would be more burdensome than the phased approach being adopted and would limit the data collected. A rule triggered by an exposure incident is reactive and not protective of employees. Non-agricultural pesticide handlers were excluded due to a lack of available evidence that indicated an equal or greater exposure risk to industries other than agriculture and also to limit the economic burden of the rule during initial implementation to the workers with the highest risk from exposures. Excluding medical removal protection from the rule would provide a strong incentive for farm workers **not** to participate in the testing program. Exempting small business or limiting the rule to commercial applicators would exclude segments of the work force often identified as at high risk.

Based on these considerations L&I concluded that the rule is reasonable and responds to concerns identified in the public process. L&I also concluded that the rule is the least burdensome alternative that will meet the statutory mandate to assure that no employee will suffer material impairment of health or functional capacity for the period of their working life. The rule is economically and technologically feasible. The department believes that the benefits of the rule will better outweigh costs than other alternatives.

### **Consequences of not adopting the rule (RCW 34.05.328(1b))**

If a rule is not adopted as part of a comprehensive strategy to address the risk of handling organophosphate and N-methyl-carbamate pesticides, the effectiveness of the strategy cannot be determined. The established underreporting of occupational illness by the worker population subject to this rule is a strong incentive for this rule. Waiting for employees to have symptoms of poisoning severe enough to seek medical attention is not an acceptable safety and health option under the WISHAct. Furthermore, while the Washington Supreme Court did not specifically order L&I to adopt a rule, the Court did direct L&I to initiate rulemaking. The additional information obtained by L&I during this rulemaking reveals the necessity of this rule.

### **Analysis of pilot rulemaking and negotiated rulemaking (RCW 34.05.310)**

The Washington Administrative Procedure Act encourages regulatory agencies to “develop and use new procedures for reaching agreement among interested parties before publication of notice and the adoption hearing on a proposed rule.” (RCW

34.05.310) More specifically, “An agency must make a determination whether negotiated rule making, pilot rule making, or another process for generating participation from interested parties prior to development of the rule is appropriate.”

L&I used a highly open and inclusive process for generating participation that included public rule development meetings and an advisory committee. Before proceeding to public hearings the department concluded that these rule development conferences and advisory committees had effectively and appropriately provided a much higher than usual degree of public involvement. Although it became clear that consensus among the multiple interested parties was not achievable, the process did successfully identify many shared ideas about possible regulatory measures that would make effective public policy. The department concluded that this represented the maximum amount of pre-proposal agreement possible and the department relied heavily upon these ideas in developing its proposal.

Negotiated rulemaking was considered and rejected for two reasons. First, negotiated rulemaking is discretionary and the process of public rule development meetings and advisory committees was an appropriate and effective alternative. Second, negotiated rulemaking is best suited to public policy issues involving a limited, easily identifiable group of affected parties who are reasonably likely to achieve consensus. The Negotiated Rulemaking Sourcebook, Administrative Conference of the United States<sup>109</sup> describes two key prerequisites for successful negotiated rulemaking: a limited number of identifiable interests affected by the rule and a reasonable likelihood that consensus can be reached.<sup>110</sup> The department concluded that the issue of cholinesterase monitoring affected parties with too widely divergent views to suggest a negotiated rulemaking would be likely to succeed.

Pilot rulemaking was considered and rejected for four reasons. First, pilot rulemaking is discretionary and the process of public rule development meetings and advisory committees was an appropriate and effective alternative. Second, pilot rulemaking is best suited to situations where an agency intends to issue a highly specific, inflexible and experimental regulation and feasibility of compliance is highly uncertain. In this case, the department decided to move ahead with a rule with demonstrated feasibility, based on sound scientific principles and data. L&I concluded that a rule designed in this manner would not benefit from pilot testing. Third, the department decided to incorporate a two-year phase-in period to allow data collection and analysis. Fourth, the rule incorporates an implementation plan including a scientific team to oversee collection and analysis of data.

### **Determination that the rule does not require actions that violate requirements of other federal or state laws (RCW 34.05.328(1e))**

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<sup>109</sup> 37 GPO 1990

<sup>110</sup> The federal Negotiated Rulemaking Act (5 USC 561 et seq) requires regulatory agency heads to consider whether “there are a limited number of identifiable interest that will be significantly affected by the rule... there is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time.”

The department has concluded that this rule does not require employers to violate any federal or state law.

**Determination that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law (RCW 34.05.328(1f))**

The WISHAct and rules adopted under it apply to local and state government employers, as well as to private employers (RCW 49.17.020(3)). The rule makes no distinction between public or private employers and the requirements are based on the presence of identified risk factors without regard to the public or private nature of the employer. In the infrequent event that a public employer is engaged in agricultural pesticide handling, the employer will be covered by the rule.

**Determination whether the rule differs from any federal regulation or statute applicable to the same activity or subject matter (RCW 34.05.328(1g))**

The federal Environmental Protection Agency (EPA) and the Washington State Department of Agriculture (WSDA) regulate pesticides, and the Department of Health (DOH) investigates pesticide exposure incidents. L&I coordinates rules related to pesticide work practices with WSDA. The regulations of EPA and WSDA do not address the issue of cholinesterase monitoring for pesticide handlers. WSDA and DOH have been actively involved in the rule development process and are working with L&I on grower outreach, recordkeeping, and other implementation activities.

**Rule implementation plan (RCW 34.05.328.3)**

**How will L&I implement and enforce the cholinesterase-monitoring rule, including a description of resources?**

This rule has a phase-in of the medical monitoring threshold, which will substantially reduce the first-year costs of the rule.

The rule includes the following implementation plan that identifies resources the department will make available.

The department will implement and complete an evaluation of this rule by doing the following:

- Organize a scientific team to oversee collection and analysis of data collected during 2004 and 2005. L&I will select representatives of the University of Washington, Washington State University, as well as other interested members of the academic and scientific communities, to participate on the team. The team will provide an initial analysis of testing data and any appropriate recommendations directly to L&I and to the cholinesterase monitoring advisory committee by November 1, 2004, and a further analysis and any appropriate recommendations by November 1, 2005. A final report and recommendations will be completed by September 30, 2006.

- Establish a cholinesterase stakeholder advisory committee to evaluate issues related to rule implementation and provider recommendations to the department regarding implementation of the rule and any possible modifications to it. L&I will invite representatives of growers, labor and other affected state agencies to participate on the advisory committee. The committee will have an opportunity to comment on the analysis completed by the scientific team and to make any appropriate recommendations before December 1, 2004, and again before December 1, 2005. In addition, the committee will review the scientific committee's final report and recommendations and provide advice to L&I prior to December 1, 2006.
- Review reports from the scientific team and stakeholder advisory committee, and other relevant information and make modifications to the rule as appropriate.
- Make efforts to defray the costs of medical testing during 2004.
- Prepare and distribute provider guidelines.
- Develop and make available a model employee training program.
- Publish a list of trained providers and certified laboratories on the Internet.
  - Coordinate recordkeeping requirements with the department of agriculture.

**How will L&I inform and educate persons affected by the cholinesterase-monitoring rule?**

L&I will provide educational resources, including model employee training and related written materials, to reduce the administrative burden of the rule on small employers.

L&I will work with the Washington Department of Health (DOH), the University of Washington (UW) and others to identify medical providers interested in providing medical monitoring activities. L&I will provide training to such providers and make their names available to growers, enabling growers to select from among such providers with a minimum of effort and to be assured that the providers are aware of the requirements of the rule and their responsibilities under it.

**How will L&I promote and assist compliance with the cholinesterase-monitoring rule?**

L&I inspectors and consultants will receive formal training on the rule in January 2004. The rule will be enforced in accordance with existing guidance related to inspections and consultations under WISHA.

L&I will work with the Washington State Department of Agriculture (WSDA) to develop recordkeeping materials that can be used for both the documentation requirements of this rule and for existing Worker Protection Standard recordkeeping requirements.

An evaluation form will also be developed that growers can use to conduct and document evaluations of their Worker Protection Program.

WSDA has posted a list of all covered pesticides on their web site and will update this list whenever necessary.

Employer workshops on the rule are scheduled throughout the state during the months of December 2003 and January 2004. Currently there are six locations scheduled Bellingham, Mt. Vernon, Yakima, Moses Lake, Okanogan, and Kennewick. The workshops will be 2 hours in length and provide an in depth description of the rule, resource materials, and an opportunity to have all questions answered.

We have drafted a workshop (Spanish and English versions) for workers who handle ChE-inhibiting pesticides. As soon as a rule is adopted, we plan to ask advocates to review and comment on this workshop as well as other outreach materials we plan to produce. We also plan to ask advocate groups to consider sponsoring, scheduling, and marketing these workshops with our assistance. We plan to deliver worker workshops in January, February and March.

We have contacted UC Davis asking for permission to modify their "Jorge's New Job" video for use in Washington. We plan to produce and distribute a Spanish-English WISHA version of this video to workers, advocate groups, growers, and to appropriate L&I staff and service locations. We also plan to use the "Jorge's New Job" video in our workshops, and to provide copies of the video to the public through our video library. We also plan to provide additional copies of the video on request to advocate groups, L&I service locations, clinics that monitor ChE levels, and to employers of affected workers. The video will be accompanied by a WISHA cover letter explaining that Washington's ChE monitoring will be similar to that depicted in the California video.

L&I will provide communications and outreach to the groups affected by the ChE rule. Currently these plans include distribution of a fact sheet, a press release, radio advertisements and public service announcements, a radio talk-show program, and possibly advertisements and rule information in Spanish-language newspapers. These communications will address the rule, the workshops, and other resources available to affected parties such as consultations, our website, and a toll-free phone number. These communications, the rule, and our outreach materials will be posted on the WISHA website. Many of these outreach communications and materials will be available in Spanish.

Staff from the University of Washington Department of Environmental and Occupational Health Science and the Pacific Northwest Agriculture Safety and Health Center (PNASH) have been working with L&I to develop the following:

- Medical provider workshops on cholinesterase monitoring.
- A Physicians manual on cholinesterase monitoring for Washington (similar to the California Guidelines for Physicians who Supervise Workers Exposed to Cholinesterase-Inhibiting Pesticides).
- An informed consent document (in English and Spanish).

Initial medical provider workshops are scheduled in December in the most highly affected geographic areas of the state. Workshops are currently scheduled for Mt.

Vernon, Yakima, Wenatchee, and Walla Walla. All providers and organizations participating in a workshop will be listed on L&I's cholinesterase monitoring web page. We are also working with the University of Washington School of medicine to provide 24-hour access to a consulting physician.

Although we currently anticipate implementing all these plans, the final mix of training and outreach products and services delivered will be determined by the director, the WISHA management team, and stakeholder needs. Among other stakeholder discussions, L&I will be holding a stakeholder meeting as required by WISHA when a significant legislative rule is adopted and implemented.

**How will L&I evaluate whether the cholinesterase-monitoring rule achieves the purpose for which it was adopted, including use of interim milestones and objectively measurable outcomes?**

L&I will work with employer representatives (including representatives of small businesses) and others to analyze the results of the rule during the first year and to consider modifications of the rule as appropriate. A scientific team consisting of representatives from the University of Washington, Washington State University as well as other interested members of the academic and scientific communities will be assembled. This team will oversee collection and analysis of the data collected during 2004 and 2005. The team will provide reports to L&I regarding rule and system efficacy, and make recommendations for rule modification if necessary. All reports from the scientific team will be made public and shared with stakeholder groups.

In addition to the scientific team, L&I will establish a cholinesterase stakeholder advisory committee. This committee will be made up of representatives of growers, labor and other affected state agencies. The committee will have the opportunity to comment on the analysis and recommendations received from the scientific team and provide advice to L&I.

L&I is working with DOH to establish a cholinesterase monitoring data system (CMDS) for the collection and analysis of test results. This system will be used to notify L&I of worker cholinesterase depressions and to provide data to the scientific team.

**Coordination with OSHA (RCW 34.05.328 (1h))**

Before adopting this rule the Department must coordinate the rule, to the maximum extent practicable, with other federal, state and local laws applicable to the same activity or subject matter.

The federal Worker Protection Standard (WPS) enforced by the Environmental Protection Agency addresses pesticide exposures, although not medical monitoring. L&I and the WSDA have identical rules that implement the requirements of the WPS. The rule being adopted complements the existing state and federal WPS requirements.

An arguably applicable law is the Occupational Safety and Health Act. This act defines the relationship between federal and state occupational safety and health agencies, including the relationship between federal and state rule making. The OSHAct requires approved state plan standards to be as-effective-as Federal standards adopted under the OSHAct in requiring employers to provide both employment and places of employment that are safe and healthful. The OSHAct also states that any approved state plan agency may assert jurisdiction over a safety and health issue with respect to which no standard is in effect under OSHAct section 6. At this time the hazards covered by this rule have not been addressed in standards promulgated under the OSHAct. Therefore there are not limitations or restrictions placed on the Department by the Federal government with respect to adoption of the proposed state standards.

L&I's occupational safety and health program functions under the jurisdiction and oversight of federal OSHA. As part of this relationship L&I meets regularly with regional and national OSHA representatives and provides regular written reports to OSHA on its activities and plans.

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**These references are representative of the evidence and underlying data in the rulemaking file for the cholinesterase-monitoring rule.**

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1.0 1.01	<b>NEED FOR THE RULE</b> The Department has concluded in the past that a mandatory medical monitoring rule was not warranted, based on best available data.  We have not seen justification health wise that shows that there are problems.	The department concluded in its 1993 rulemaking that mandatory medical monitoring was not appropriate based on the record before it at that time. In 1997, the department chose not to pursue medical monitoring rulemaking because of its regulatory priorities, but did <i>not</i> determine that such a rule was not appropriate or warranted. Although accepting the 1993 decision, the <i>Rios</i> Court ruled that L&I's failure to initiate rulemaking in 1997 was a violation of WISHA.  The department's reasons for adopting a rule based on the current record, including the occupational health justifications for the rule, are described in more detail in the main body of the Concise Explanatory Statement (CES). The department has relied upon the best available data to analyze the feasibility and appropriateness of using blood cholinesterase levels to monitor exposure to organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides.  The preponderance of research establishes the link between exposure to organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides and cholinergic poisoning. Acetylcholinesterase inhibition in the nervous system is viewed as a key event in the mechanism of toxicity of these compounds.  The Environmental Protection Agency has accepted the use of blood cholinesterase measures as surrogates for cholinesterase levels in the nervous system ( <i>The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides</i> , 2001). The State of California, the United States Military and many universities use routine blood cholinesterase measurements to monitor exposure to cholinesterase-inhibiting agents.  There are reliable, commercially available laboratory methods, such as the Ellman and Michel assay methods that can be used to routinely analyze samples in large cholinesterase monitoring programs. Studies have demonstrated wide variability in test results and difficulty in comparing test results when different methodologies are used for baseline and periodic testing of an individual's blood

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		cholinesterase levels. This variability necessitates the use of a single testing methodology within any cholinesterase-testing program.  As discussed in the main body of the CES, the department has concluded, based on the present record, that its reasons for choosing not to require monitoring in 1993 no longer apply.
1.02	...It's our belief that the Supreme Court did not direct Labor & Industries to adopt a rule.	The Supreme Court directed the department to initiate rulemaking on a mandatory cholinesterase-monitoring rule for agricultural pesticide handlers consistent with the Court's analysis of the law in <i>Rios</i> . The department considers the proposal of the rule to have complied with the <i>Rios</i> order, but recognizes that the department's analysis of the present record must be consistent with the Court's reasoning. The Administrative Procedures Act (APA) requires that the Department's decisions regarding the rules be based upon a consideration of all the evidence before it. In the absence of evidence that indicates a lack of benefit or that cholinesterase monitoring is not technologically or economically feasible, the record supports a decision to implement a cholinesterase-monitoring program. The department has made its decision based on the present record, as discussed in more detail in the main body of the CES.
1.03	As the Supreme Court observed, in 1995 L&I's own team of technical experts found that in light of the most current research a monitoring program is both necessary and doable.  ...the best currently available evidence continues to demonstrate that cholinesterase monitoring is feasible and appropriate, and therefore required under RCW 49.17.050(4).	The Court did indeed conclude that the 1995 Technical Advisory Group (TAG) report found monitoring to be both necessary and doable. However, the department's decision to adopt a rule is based on the entire record before it in the present rulemaking, not the findings of the TAG report.
1.04	Organophosphate and carbamate pesticides are extremely dangerous neurotoxic agents. Organophosphates and carbamates are among the most often implicated pesticides in causing symptomatic illnesses. This proposed rule covers some of the most toxic pesticides still used in agriculture;	The rule requires that medical monitoring be provided to agricultural workers who handle toxicity category I or II organophosphate and N-methyl-carbamate pesticides. Toxicity categories are mainly based on the amount of a substance that would kill 50% of an exposed population. This is called the "lethal dose 50" or

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	<p>pesticides that represent unacceptable risks to the health of people who handle these dangerous substances under current use patterns.</p> <p>Thus, L&amp;I should move expeditiously to finalize the proposed rule, as amended by these comments; develop and implement a vigorous enforcement plan to ensure compliance with the rule; and, utilize the data collected, in conjunction with involvement from citizens' groups, to increase protections for workers in the future.</p>	<p>LD 50. The LD 50 of a substance is expressed in terms of milligrams of the substance per kilogram of body weight. Toxicity category I pesticides have an LD 50 of <math>\leq</math>50 milligrams/kilogram of body weight. Toxicity class II pesticides have a LD 50 of 51-500 milligrams/kilogram.</p> <p>Toxicity category I and II cholinesterase inhibiting pesticides are highly toxic and are frequently implicated in pesticide poisoning in agricultural workers. Because of the demonstrated hazards associated with toxicity category I and II cholinesterase inhibiting pesticides it is reasonable to limit medical monitoring to only those workers who handle toxicity category I and II cholinesterase-inhibiting pesticide.</p> <p>The rule implementation plan, found in WAC 296-307-14845 and discussed in greater detail in the main body of the CES, requires the department to establish a scientific team and a stakeholder advisory group to evaluate cholinesterase test results and issues related to rule implementation. These groups will provide recommendations to the department.</p>
1.05	<p>A study by Washington State University found that the state's apple and pear growers greatly reduced their use of pesticides in the past decade (Wenatchee World, Oct. 6, 2002). Some of the decrease resulted from federal regulations restricting the use of the most toxic pesticides, but the study also showed that growers successfully adopted safer methods of pest control, including insect monitoring and biological mating disruption. The use of Guthion, one of the most widely used pesticides for tree fruit, has dropped by nearly 40 percent since 1989. L&amp;I has not considered the reduced use of organophosphate chemicals in its decision to propose a regulation.</p>	<p>Some changes in pesticide use patterns have occurred. Some of the most highly toxic cholinesterase-inhibiting pesticides, such as Phosdrin, are no longer used in Washington State. However, organophosphate and N-methyl-carbamate pesticides are still widely used in Washington State. For example, the EPA reports that in 1997 1,615,000 pounds of organophosphate pesticides were used on orchards in Central Washington State. The department has concluded that the evidence indicates that the use of toxicity class I and II organophosphate and N-methyl-carbamate cholinesterase inhibiting pesticides remains a significant industry hazard. While the decrease in use of covered pesticides reduces potential exposure overall, it does not decrease the potential exposure for those individual workers still using such pesticides at levels covered by the rule.</p>
1.06	<p>Because farm workers have been denied medical monitoring until now, cholinesterase data in our state is scant. Nonetheless, a study of 95 workers found that approximately 7 to 8 % had cholinesterase depressions consistent with significant depressions. Over 11% of the applicators tested were found</p>	<p>As discussed in more detail in the main body of the CES and the Benefit Cost Determination (BCD), the rule can be expected to provide a number of benefits, and a certain amount of quantitative information is available for certain benefits – such as the number of workers likely to be identified and treated for cholinesterase</p>

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	<p>to have significant depressions. (These are depressions that would trigger workplace investigations and/or removals under the draft rule.) These results are particularly significant because participation by growers in the study was voluntary. Those willing to volunteer may have been more likely than other employers to comply with worker protection standards and otherwise protect workers.</p> <p>While cholinesterase testing has been rare in Washington, the University of Washington, Fred Hutchinson Cancer Research Center, and other entities have collected other data indicating significant exposures to organophosphates (OPs) and carbamates (CBs) for farm workers. Organophosphate metabolites were found in the urine of 92% of 213 workers tested in a study published this year, for example. Referring to a survey of 553 workers, the authors noted that “...one hundred percent of pesticide handlers reported being exposed to pesticides while performing that job task... Monitoring is a basic protection offered in other workplaces in which workers handle highly toxic chemicals. Given the extreme toxicity of the chemicals they are handling, farm workers deserve monitoring as an essential safeguard to reduce the risk of serious injury or death. L&amp;I must adopt the proposed rule in order to address a major deficiency in farm worker protections and a serious inequity as compared to other workplaces.</p>	<p>depression as a result of the rule. However, available information about most of these benefits makes it impracticable to quantify them with any level of confidence at this time.</p> <p>In regard to the primary goal of preventing illness, L&amp;I has estimated that medical monitoring will identify cholinesterase depressions that would trigger medical removal in between 1.2 and 4.8 percent of participating employees, with a central estimate of 3 percent, at least during the first years that such monitoring is required. If 85 percent of eligible employees participate in the medical monitoring, the central estimate suggests that the rule will identify 37 employees with depressed cholinesterase levels in the first year, and 95 beginning in the second year. This allows employers to remove these employees from exposure before symptoms occur and to correct any identified program deficiencies thereby preventing further exposures and illness.</p>
1.07	<p>The EPA's Reregistration Notice on Worker Risk Mitigation for Organophosphate Pesticides shows that margins of exposure for a number of these pesticides exceed the agency's level of concern, even with maximum personal protective equipment or engineering controls.</p> <p>• • • . . .</p> <p>The Worker Protection Standards do not eliminate the need for cholinesterase monitoring.</p>	<p>The EPA assessment of risk for organophosphate and N-methyl-l-carbamate pesticides can be summarized as indicating that many injurious exposures to handlers can generally be avoided by properly worn PPE and properly used engineering controls</p> <p>A basic premise of any medical monitoring program is the inherent unreliability of PPE and engineering controls. The department mandates the use of engineering controls in many instances because they are more reliable than PPE; however, these controls generally require maintenance and they are subject to failure. For this reason WISHA also mandates appropriate medical monitoring of workers to ensure the workers are provided effective protection. The most prevalent problem</p>

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		<p>identified by the EPA assessment (as well as by comments from worker advocates and by growers) is failure to use the required PPE. Even when PPE and engineering controls are used properly questions can be raised about their effectiveness and cholinesterase monitoring will help to assess this effectiveness.</p> <p>The department has concluded that a well-run cholinesterase-monitoring program will be an effective tool for identifying exposures that occur despite the existence of the Worker Protection Standard and for ensuring that the existing requirements of the Worker Protection Standard are followed. Cholinesterase monitoring, like any medical monitoring program, will function in tandem with appropriate PPE, work practice and engineering control requirements.</p>
1.08	The agriculture industry has responded to risks of pesticide exposure and has taken great strides to nearly eliminate exposure to organophosphates and carbamates to handlers. That has been seen in training programs, the modification of the packaging of pesticide, and the engineering and modification of pesticide application equipment. All of those modifications have resulted in increased costs to the farmer. Application equipment is inspected and certified to nearly eliminate exposure to the at-risk handler of these pesticides. Exposure to pesticides by farm workers has decreased as a result of these efforts.	The Agriculture industry has taken steps to reduce the hazards associated with handling cholinesterase-inhibiting pesticides. The fact that positive work has been done does not sufficiently eliminate the hazards associated with working with toxic chemicals. The exposure hazard still exists and exposures still occur. Equipment failure, accidental spills, misuse or non-use of personal protective equipment, and poor decontamination practices are all factors that contribute to the risk of exposure. The department has concluded that a cholinesterase monitoring program will not only reduce exposures in the agriculture industry but will also be a useful tool for employers to verify the efficacy of their implementation of the pesticide Worker Protection Standard.
1.09	Last year I spent a month spraying Roundup and I was spraying four other chemicals that were mixed with the Roundup. The conclusion I want to reach is I worked at that farm and they never gave me any PPE, Personal Protective Equipment. I had to buy boots and eye protection, mask, and everything. I worked for a complete month. My entire throat was damaged. This rule is very important for us as workers because I used to work 60, 70 hours a week. It's a very important rule for us	This is covered by the Worker Protection Standard in chapter 296-307 WAC. The use of herbicides, such as Roundup, and appropriate PPE is not within the scope of the cholinesterase monitoring rule.
1.10	Based on the data from 2000 and 2001, L&I is proposing a regulation that may have some impact on 7 or less relatively minor workers' compensation claims each year. Amazingly, the workers' comp data was not used to develop expected medical removal rates or even considered when the	A review of 2000-01 PIRT and L&I claims data found that there were a total of 195 agricultural pesticide related claims compared to a total of 77 non-agricultural pesticide claims. Of the 195 agricultural claims the Washington State Pesticide Incident Report Tracking (PIRT) panel classified 94 as definite, possible or

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	<p>department decided to propose this rule.</p> <p>It also should be noted that actual data from the Washington State Department of Labor &amp; Industries indicates that in 2000 only three compensable claims occurred, in 2001 only one. Placing a \$2.8 million dollar expense on growers to address such a small number of claims is not justified.</p>	<p>probable exposures. Organophosphate or N-methyl carbamates were found to be involved in 34 of these exposures.</p> <p>As discussed in more detail in the main body of the CES and the BCD, as well as in the specific response to comments by the Washington Farm Bureau, the primary purpose of this rule is to address exposures that are not likely to be reported as industrial insurance claims. As comments have indicated, the type of exposure reflected by the claims data is generally both acute and high enough to cause symptomatic illness, while a medical monitoring program is intended to identify early, asymptomatic exposures, whether acute or chronic. Given that context, it would have been clearly inappropriate to use those acute exposure claims to estimate medical removal rates for chronic exposures. As is typical of occupational disease exposures and as appears to be a particular problem with pesticide exposures, claims data is not a reliable indicator of how many low-level or long-term exposures occur that cause illness but do not result in the employee seeking medical care or are otherwise not diagnosed as related to pesticide exposure.</p>
1.11	<p>Alan Felsot, PhD, studied the likelihood of exposure that would trigger a work-related removal due to cholinesterase depression using EPA data. Dr. Felsot's work is significant because L&amp;I has not done any systematic analysis of the EPA data. After studying EPA data, Felsot concluded: For organophosphorus (OP) pesticides that account for the majority of insecticide use, the EPA concluded that levels of exposure are below the levels that will inhibit the blood enzymes cholinesterase or acetylcholinesterase.</p>	<p>One of the clear and obvious benefits of the rule is that a comprehensive medical monitoring program can address the relative uncertainty regarding the number of employees with cholinesterase depression. In addition, currently undiagnosed cases can be brought into the workers compensation system as a result of the ongoing monitoring program.</p> <p>The comment inaccurately interprets the EPA conclusions and exaggerates Dr. Felsot's analysis. Dr. Felsot's summary states, "According to EPA's analyses, use of recommended personal protection equipment (PPE) would prevent measurable cholinesterase depression. Given the expected low levels of worker exposure when proper PPE is used, medical diagnostic laboratories will face great difficulties in determining any changes in cholinesterase activity from pre-work baseline levels. Thus, medical monitoring is unlikely to help identify workers at risk as a result of exposure to enzyme inhibitory levels and associated analytical problems."</p>

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		<p>The department agrees that appropriate use of PPE as mandated by the Worker Protection Standard should be sufficient protection to avoid cholinesterase depression in the majority of cases. Unfortunately, appropriate and consistent use of PPE does not always occur, and the EPA has identified the failure to use PPE as a major ongoing problem in the industry. As discussed in more detail in the main body of the CES, the department has concluded that a well-run cholinesterase monitoring program will be an effective tool for identifying exposures that occur despite the existence of the Worker Protection Standard and will work in tandem with existing PPE, work practice and engineering control requirements to prevent cholinesterase poisoning.</p>
2.0	<b>SCIENTIFIC EVIDENCE</b> The department has not evaluated the best available data. If the department objectively examines all of the available data, the result will be a determination that the department was correct in 1993 and 1997 that a mandatory testing regulation is not warranted.	<p>The department concluded in its 1993 rulemaking that mandatory medical monitoring was not appropriate at that time based on the record before it. In 1997, the department chose not to pursue medical monitoring rulemaking because of its resource priorities, but did <i>not</i> determine at the time that such a rule was not warranted. Although accepting the 1993 decision, the <i>Rios</i> Court ruled that L&amp;I's failure to initiate rulemaking in 1997 was a violation of WISHA.</p> <p>In considering the present record, the department has evaluated the best available data to analyze the feasibility and appropriateness of using blood cholinesterase levels to monitor exposure to organophosphate and N-methyl-carbamate cholinesterase-inhibiting pesticides.</p> <p>Based on the body of evidence collected by the department and submitted by various stakeholder groups the department has concluded that there remains a significant risk to agricultural pesticide handlers. Cholinesterase monitoring provides additional and appropriate protection; further, the department has concluded that cholinesterase monitoring is both technologically and economically feasible.</p>
2.02	...we're concerned that the premise used to justify this rule is out-of-date information from California, data which does not reflect Washington's specialized agricultural and pesticide-use patterns. Before this rule	The department has paid close attention to data from California because California is the only State that has a mandatory cholinesterase monitoring program in place, and has had this program in place since 1974. The department is aware that

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	<p>proceeds, it should be based on Washington-based data.</p>	<p>California conducts no formal, ongoing evaluation of their cholinesterase monitoring program and that much of the available California research has been conducted with data generated in the 1980's. However, the department has considered all information in the record, including information about use patterns in Washington state.</p> <p>The department is aware of recent preliminary data from California that indicates the rate of medical removal appears to have decreased from the rates reported in the late 1980's and early 1990's. This would be expected given such factors as the introduction of the Pesticide Worker Protection Standard and changes in pesticide use patterns. Medical removal rates would also be expected to decline as California's cholinesterase monitoring program works in tandem with the WPS requirements related to PPE, work practices and engineering controls and becomes more effective in increasing awareness of pesticide hazards and allowing growers to make corrections in their worker protection programs.</p>
2.03	<p>Based on data from the EPA, California, PIRT, Washington workers' comp, independent medical doctors and companies currently conducting cholinesterase monitoring, and independent studies with data collected after 1993, we can draw the following conclusions:</p> <ul style="list-style-type: none"> <li>• The number of workers who will be injured or face medical removal due to work related cholinesterase depression is extremely small - from 0 – 1%</li> <li>• There will be a significant number of abnormal cholinesterase tests – in the 3-10% range. This is due to the imprecision of the test, the large fluctuation in individual levels of cholinesterase, and other variables.</li> <li>• Prior to adoption in 1993 of personal protective equipment regulations,</li> </ul>	<p>As discussed in more detail in the BCD, the department considered these factors along with differences in the agricultural industries of California and Washington (e.g., differences in the length of growing seasons) in establishing the expected medical removal rates used in the Small Business Economic Impact Statement and Benefit Cost Determination.</p> <p>The conclusions represented in the comments are based on recurring misunderstandings of the data. The comment assesses all cholinesterase information by misapplying information about experimental testing methods (not used by this rule) and testing methods relying upon laboratory normal standard rather than baselines (the approach used in this rule). The problems cited do not apply to the sampling and analytical approach used by this rule. These issues are discussed in more detail in the BCD and in the detailed response to comments from the Washington Farm Bureau.</p> <p>The department calculated medical removal rates based on the most recently published medical removal rates from California, which provides the only large,</p>

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	<p>changes in pesticide formulations, and the industry practice of limiting pesticides, there were more frequent exposures and would have resulted in more medical removals</p> <ul style="list-style-type: none"><li>• Lab results for ChE testing are currently not reliable.</li></ul> <p>Given this overwhelming evidence, L&amp;I assigned a medical removal rate of 3%. A more accurate medical removal rate would be in the 0.5% range. Please provide an explanation, using post-1993 data, which led the department to assume that 3% of workers will be medically removed...</p>	<p>state run cholinesterase-monitoring program for comparison. Ames, et al, 1989, found a 4.8% medical removal rate. The removal thresholds used in California at that time were 10% lower than those in the Washington rule, so removal rates would be expected to be somewhat higher. In addition, the California monitoring rule had been in place for more than 10 years when this data was gathered, and would be expected to reduce the number of depressions identified over time. However, the group evaluated did not necessarily represent exposures addressed by the Washington rule, particularly in the first year when the threshold for monitoring will be triggered by 50 hours of covered handling, rather than 30 hours.</p> <p>The department reviewed this information and considered stakeholder comments about the increased use of closed systems, reductions in the use of the most hazardous pesticides, the more stringent worker protection requirements in place today compared to 1989, and the employer incentive to avoid the cost of removal created by the medical removal protection requirement itself. Based on this review, the department has concluded that the 4.8 percent removal rate is a high range and that the likely range can be expected to approach half that rate.</p> <ul style="list-style-type: none"><li>• The central cost estimate assumes a 3.0 percent removal rate.</li><li>• The low cost estimate assumes a 1.2- percent removal rate.</li><li>• The high cost estimate assumes a 4.8 percent removal rate.</li></ul> <p>If the 5 percent removal rate suggested by the comment were used, the cost estimates for the rule would be reduced below even the low cost estimate. However, the department does not expect the removal rate to be that low in the initial years of the rule's existence (although it is likely that medical monitoring, working in tandem with existing PPE, work practice and engineering control requirements, will reduce overexposures and the resulting cholinesterase depressions – this in turn will reduce the cost of the rule in future years, although the department did not quantify such a reduction in its estimate of the rules' costs).</p>

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		<p>The reliability of cholinesterase laboratory testing is well established (Kreiger, R.I. (2001). Handbook of Pesticide Toxicology). The misunderstanding reflected in these comments regarding laboratory testing reliability and false depressions is related to the use of "laboratory normal" values to determine cholinesterase depression, to the evaluation of field test kits, and to the evaluation of the use of blood samples taken outside a clinical environment. Cholinesterase tests without comparative baseline measurements are not independently considered a valid indication of cholinergic depression, the field test kits were not found to be reliable methods for field use, and blood samples taken outside the clinical environment were found to be subject to improper handling. None of these unreliable approaches have been taken by this rule as adopted.</p>
2.04	We are concerned about protecting the health of pesticide applicators. The best way to provide that protection in the immediate future is to use properly designed protective equipment and professional pesticide handling procedures, and to provide well-designed, regular training to applicators. In the long run, a medical monitoring program may have a place for some pesticide applicators, but it is important that the state determine at what exposure threshold monitoring actually becomes a benefit to pesticide handlers, and to base the regulation on that data.	<p>The department agrees that future exposure thresholds should be based on analyses of exposure data and related issues under the rule. The cholinesterase monitoring rule has established an exposure threshold of 30 or more hours in any consecutive 30-day period, but the threshold is phased in and includes only those handlers with 50 or more hours in any consecutive 30-day period for the first year of implementation.</p> <p>These exposure thresholds are largely based on an exposure threshold established by California and used effectively in that state. However, these thresholds also reflect accepted clinical practice and were generally agreed to by the cholinesterase monitoring stakeholder advisory group as reasonable starting points. One alternative to identifying such reasonable exposure thresholds for purposes of rule implementation is to require all agricultural workers who handle cholinesterase-inhibiting pesticides to be monitored on a routine basis regardless of exposure time, since all such handlers have some potential exposure. This approach would result in employees at low-risk for overexposure to be tested and would place an undue hardship on both growers and employees.</p> <p>The department has committed to analyzing cholinesterase test results during the 2004 and 2005 calendar years. If the data indicates a more appropriate exposure threshold (either higher or lower) than 30 hours in any consecutive 30-day period</p>

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2.05	The need for cholinesterase monitoring has been clearly demonstrated. Nearly one fourth of those tested in California were found to have significantly depressed cholinesterase levels in major reviews of test results there. As you know from information previously submitted by Columbia Legal Services and others, the types and quantities of pesticides used in California at the time of data collection were very similar to those currently used in Washington State. At the time that tests were done, California had already implemented the sorts of worker protection standards currently in place in Washington State. Indeed, California had and continues to have in place more stringent requirements than Washington, such as closed system requirements for Category I and II pesticides.	then the rule will be amended as necessary.  Independent research conducted in California in the late 1980's and early 1990's has shown medical removal rates of up to 24% in specific study populations, but the department does not believe that level of poisoning is occurring in agricultural pesticide handlers in Washington. It is difficult to extrapolate these research results over the larger population of agriculture workers being monitored in California and directly correlate these findings to current situation in both California and Washington. Regardless of the difficulty in assigning probable medical removal rates, the studies done in California clearly indicate that cholinesterase monitoring has been effective in identifying overexposure to cholinesterase-inhibiting pesticides and removing workers from further exposure before illness occurs.
2.06	...Since this issue was raised by farm worker advocates, significant changes have taken place. The worker protection Standard was put into place. Use of organophosphate pesticides has decreased dramatically. These two events have drastically reduced the potential for exposure. We do not believe that these events were given adequate weight in the rule development process.	The department understands that California's closed system requirement applies only to Category 1 pesticides. This rule applies only to medical monitoring and is not intended to address specifically the use of closed systems. Closed systems usage may be the subject of future rulemaking, if the department deems necessary.  Even with the introduction of the Worker Protection Standard organophosphate and N-methyl carbamate pesticides continue to cause significant morbidity in the agricultural sector, as indicated by the annual American Association of Poison Control Centers and the California Pesticide Incident surveillance Program reports. The Washington state Pesticide Incident Report Tracking (PIRT) Panel reports an average of 10 cholinesterase-inhibiting pesticide exposures per year in agricultural pesticide mixer/loader/applicators. While these reported illnesses are generally the result of acute exposures that would not necessarily be affected by the rule, they do indicate that the risk of poisoning remains a real one. Research indicates that very few actual exposure incidents are reported to state databases.  Though the use of organophosphate pesticides has decreased, they continue to be one of the most widely used classes of pesticides in Washington State. Reduction in overall use does not remove the hazard to those agricultural workers who are still handling organophosphate and N-methyl-carbamate pesticides.

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2.07	Washington's Pesticide Illness Reporting and Tracking (PIRT) data, while limited, consistently shows that mixing, loading, and applying pesticides results in farm worker illness.	<p>As discussed in more detail in the main body of the CES, the department has considered these factors in light of the record and has determined that significant risk exists and that cholinesterase monitoring is an appropriate protection.</p> <p>The PIRT Review Panel consists of representatives from the Department of Agriculture, Department of Ecology, Department of Health, Department of Labor &amp; Industries, the University of Washington, Washington State University, the Washington Poison Center, a toxicologist and a member of the public. It was formed to ensure that state agencies responsible for pesticide regulation coordinate their incident investigations, reporting, and education activities in a timely manner to protect workers and the public from pesticide misuse.</p> <p>Analyses of PIRT data from 1997 through 2001 indicate that 52 definite, possible, or probable exposures occurred to agricultural workers while mixing, loading, or applying cholinesterase-inhibiting pesticides. PIRT data reflects reported incidents of pesticide illness, generally acute exposures that result in medical care. Therefore, we cannot make conclusions regarding the exact extent of low-level exposures that may be occurring while handling cholinesterase-inhibiting pesticides.</p> <p>The main body of the CES and the BCD discuss the basis for concluding that the reported illnesses, which may not themselves be directly addressed by the cholinesterase monitoring rule, represent only a small fraction of the likely effects of poisoning by covered pesticides. For example, a recent focus group study conducted by the Washington State Department of Health (Summary Results of Yakima Farmworker Focus Groups About Pesticides and Health Care, 2003) concluded that:</p> <p style="padding-left: 40px;">“It was clear from listening to these farmworkers that many of them experience illnesses they believe are due to pesticide exposure, and that they are reluctant to seek out health care for mild to moderate illnesses because of the costs, fear of job loss, and lack of trust in</p>

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2.08	There is no data or any study in Washington that evaluates cholinesterase depression in pesticide applicators wearing currently required protective equipment.	<p>their health care providers in diagnosing and treating pesticide related symptoms.”</p> <p>This is consistent with other studies that indicate that pesticide related illness – and occupational illness in general – is under reported.</p> <p>The department has found only one such study specific to Washington State, by Karr, et al, and the department does not argue that cholinesterase depression is likely to occur if workers meet the current PPE, work practice and engineering control requirements. One of the benefits of mandatory cholinesterase monitoring is that it will make such studies possible and will assist in the identification of problems both with required PPE and its appropriate use. However, the department does not believe that such a study is in any way necessary to justify the rule. Research indicates that, despite the requirements of the Worker Protection Standard, inconsistent compliance remains (e.g., Schenker MB, Orenstein MR, Samuels SJ. (2002). “Use of protective equipment among California farmers”. <i>American Journal of Industrial Medicine</i>. &amp; Perry MJ, Layde PM (1998). Source, routes, and frequency of pesticide exposure among farmers. Journal of Occupational and Environmental Medicine.) As discussed in the main body of the CES, cholinesterase monitoring – like any medical monitoring program, can be expected to function in tandem with current requirements to ensure that workers are protected.</p>
2.09	In 1995, Keifer, et al, did a study of 80 workers from six orchards that were heavily exposed to organophosphates and carbamate pesticides. The study was undertaken for L&I. Keifer was unable to identify a single worker who would have been removed due to work related cholinesterase depression... In this study, Karr, et al, used a finger prick field test kit to test 95 workers over one season. They identified 9 workers with depression that would require a workplace investigation, and subsequently determine that 3 of the 9 were unrelated to workplace exposure. They next determined that the test kit was not reliable for plasma ChE testing, thus eliminating three more results where only plasma ChE depression was observed...	<p>The department has reviewed these studies, and discusses them in more detail in the specific response to comments from the Washington Farm Bureau. While all three studies provide valuable information they do not have direct application to a laboratory-based cholinesterase monitoring program as provided for in the cholinesterase monitoring rule (nor was the primary purpose of any of them to identify the extent of cholinesterase depression in pesticide handlers).</p> <p>All three studies used portable test kits to conduct field-testing of various agricultural worker populations, including harvesters, thinners, and other worker not involved in pesticide handling activities. One study also used laboratory analysis of blood samples taken in the field (rather than in a clinical setting). The</p>

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	<p>(Simcox, et al, 1999, American Industrial Hygiene Journal)      Here is another study with the same result - zero work related OP illness.      In this study of field workers during tree fruit thinning, attempts to measure ChE depression were unsuccessful due to an unreliable testing kit, a common problem. There were zero symptoms of ChE depression and no reports of any OP related illness. One quarter of the test participants did not complete this 4 to 6 week study.</p>	<p>primary purpose of two of these studies was to evaluate the usefulness of using a field test kit to monitor cholinesterase levels. Given that these two studies concluded that the field test kit was not a practical reliable substitute for laboratory testing, they cannot be relied upon as a basis for determining the level of cholinesterase depression. The Simcox study evaluated exposure to residues in apple thinners. The study is not relevant to the rule since the field test kit will not be used and since tree fruit thinning is not pesticide handling (and therefore is not covered by the rule).</p>
2.10	<p>Surveys of Washington farm workers indicate widespread pesticide-related illness, and widespread non-reporting of that illness due to serious barriers faced by farm workers.</p>	<p>As discussed in the main body of the CES and the BCD, it is well documented and generally accepted that illnesses due to pesticide exposure are underreported, as are occupational illnesses in general. The extent of underreporting is not precisely known. A recent farmworker focus group study in Washington State found that more than three-fourths of participating farmworkers felt that they had experienced symptoms resulting from exposure to pesticides while on the job. While many participants believed they had experienced pesticide-related symptoms, few sought care for them (Vanderslice, Baum, Bonnar-Prado, Bardin, Hanks. 2003). While the nature of the study and its reliance on focus groups make it difficult to draw exact statistical information from the results, they confirm a wide body of information on the under-reporting of occupational illness in general and pesticide exposures in particular.</p>
2.11	<p>The principal reason for the Supreme Court ruling in <i>Rios</i> was the work of TAG...requests an investigation of the false statements in the TAG report. In addition, .. requests that the department form a more balanced group of experts to produce a more accurate report of the research concerning this topic.</p>	<p>One of the clear an obvious benefits of the rule is that the relative uncertainty regarding the number of employees being poisoned can be improved by a comprehensive medical monitoring program. In addition, currently undiagnosed cases can be brought into the workers compensation system as a result of the ongoing monitoring program.</p> <p>The department cannot speak for the Supreme Court in regard to the weight it gave the TAG report in the <i>Rios</i> decision. However, the department's conclusions in this rulemaking are based on the record and the body of evidence currently before it, not the findings of the TAG report.</p>

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		Although the TAG report included a potentially erroneous statement summarizing the Karr data, L&I does not agree with the characterization of this error implied by the phrase “false statements,” nor does L&I believe an “investigation” is necessary.
3.0	<p><b>Small Business Economic Impact Statement (SBEIS)</b></p> <p>Based on data available, it appears that the costs to implement this program far exceed the benefits. If the rule is adopted, employers and workers will spend millions of dollars each year related to a medical monitoring system. The majority of the cost will be associated with investigations that determine that the testing procedure was flawed.</p>	<p>This statement reflects a misunderstanding of the difference between analyses that rely upon “laboratory normal” levels, which are unreliable, and the baseline approach used in this rule, which is reliable and reflects accepted clinical practice. As discussed in more detail in the specific response to the Washington Farm Bureau comments, the department disagrees with the expectation that medical monitoring will result in any meaningful level of “false positives.”</p> <p>The comment misunderstands the purpose of the SBEIS, which is not an analysis of the costs and benefits of the rule.</p>
3.01	<p>The SBEIS did not fully consider whether compliance with the rule will cause agricultural employers to lose net revenue, as required by RCW 19.85.040(1), because the SBEIS considered only the estimated <u>costs</u> of the rule, L&amp;I knowingly used overstated cost estimates, and L&amp;I failed to offset these potential costs with the rule’s known and reasonably expected economic benefits to agricultural employers.</p> <p>The SBEIS statute states, “A small business economic impact statement...shall consider...whether compliance with the rule will cause businesses to lose...revenue.” RCW 19.85.040(1). The term ‘revenue’ is defined as, “[A] gain or recurrent benefit usually measured in money that derives from capital or labor; also: the amount of such gain received in a period of time.” Merriam-Webster’s On-Line Dictionary (available at <a href="http://www.m-w.com">http://www.m-w.com</a>). Essentially, the SBEIS statute requires L&amp;I to determine the impact of a rule on a business’s bottom-line.</p> <p>In order to determine the rule’s impact on revenue, L&amp;I must examine the rule’s cost on small businesses that use covered pesticides and then subtracted those expected costs from the expected net profit of those same small businesses. L&amp;I examined the potential “costs using data available from the [agency’s] survey [of effected businesses] and from other sources... L&amp;I [also] used a set of ‘reasonable’ assumptions to generate a most probable central value... [and] a low and high estimate...” SBEIS, 7</p>	<p>Among other things, the Regulatory Fairness Act requires consideration of the impact on <i>revenue</i>, which the commenter has confused with the impact on overall <i>profits</i>, what the commenter calls the “bottom line.” The SBEIS did not discuss benefits, nor was it required to do so. The process of defining both the costs and the benefits is reflected by the benefit cost determination required by the Administrative Procedure Act – although not required, a draft of that determination was provided for public comment at a later point in the process.</p> <p>The commenter also inappropriately combines the RFA’s expectation that the department assess the impact on revenue with the separate RFA requirement that the department determine whether the rule would create a disproportionate impact on small business.</p>

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	<p>(emphasis added). L&amp;I described a number of potential costs resulting from the rule, including “Wages and Benefits,” “Recordkeeping,” “Training,” “Baseline Testing,” “Period Testing,” and “Medical Removal” costs associated with the rule. <i>Id.</i> 7-14. However, after estimating these costs, L&amp;I failed to take the next, necessary analytical step of determining whether the potential benefits of the rule would offset or reduce the potential costs. L&amp;I is required to take this step to accurately estimate whether the proposed rule would have a disproportionate impact on the <u>revenue</u> of small businesses. Instead, L&amp;I ignored this statutory mandate and made the disproportionate impact determination based on “Central Cost Estimates.” <u>SBEIS</u>, 16 (emphasis added).</p> <p>L&amp;I compounded this error by using cost estimates that clearly overstate the effect on businesses in Washington. In fact, the department admits that its cost assumptions “clearly overstates employer costs” and that L&amp;I failed to consider known factors that would reduce costs, such as “businesses who do not use [ ] covered pesticides.” <u>SBEIS</u>, 8 and 16. This represents a considerable overstatement, since the acreage of farms in Washington using organic agricultural methods has increased for a number of years.</p> <p>L&amp;I used numerous other assumptions that overstated employer costs.</p> <p><u>SBEIS</u>, 8 (“L&amp;I developed the central value by excluding the 2 users at the 30 to 60-hour interval, leaving 2 handlers at the 61 to 100 level as the most likely number.”); (“[T]he current analysis assumes that all handling hours will be covered by the periodic testing requirement, which is likely to overstate the cost of the rule to at least some degree.”); (Although such a shift was predicted by a meaningful number of respondents (see Table 2), this analysis does not reflect the resulting reduction in employer costs.</p> <p>Instead, it treats the cost of the shift as essentially identical to the cost of complying without any change in work assignments. This clearly overstates employer costs.”). Moreover, L&amp;I’s disproportionate impact finding relates only to professional applicators, a small segment of all small businesses, and the small business category that had greater than 1- percent impact under the rule. <u>SBEIS</u>, 16 n.7 (“a disproportionate impact on small business was</p>	<p>This has no effect on the total compliance costs of the rule. L&amp;I did not include businesses that do not use pesticides in calculating the total costs of the rule. L&amp;I also did not include those businesses, which are not covered by or affected by the rule, in calculating the per business cost of the rule. L&amp;I believes this is the most appropriate way to assess the impact, particularly as it relates to the potential for disproportionate impacts on small businesses.</p> <p>L&amp;I took a conservative approach to assessing the costs, acknowledging in several places where the costs were likely to be somewhat lower than those reflected in the SBEIS. It is not clear how this conservative approach, which was applied to both the large and small growers in each sector, would lead to an incorrect conclusion as to the potential disproportionate impact.</p> <p>As required by law, L&amp;I analyzed the cost impacts by industry sector. L&amp;I determined that a disproportionate impact existed in the professional applicators sector. The commenter appears to suggest that L&amp;I should have disregarded this finding because that sector is small and L&amp;I did not find a disproportionate impact elsewhere. But the commenter is in error – L&amp;I analyzed by sector and reached a</p>

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	<p>considered to exist if the estimated cost per covered pesticide handler was more than 10 percent greater for small business than for the largest 10 percent of businesses in the same industry sector. However...no central value comparative impacts above 1 percent were found other than those in the professional applicators.”) (emphasis added).</p> <p>1.</p> <p>In short, L&amp;I failed in the SBEIS to account for a wide range of benefits that a medical monitoring rule will provide to Washington’s businesses. Therefore, the SBEIS contains an arbitrary and artificially narrow examination of impacts that will flow from a medical monitoring rule. L&amp;I should integrate the benefits described above into its analysis of whether the rule will disproportionately impact the revenue of small businesses. By correcting these omissions, L&amp;I will come one step closer to complying with the SBEIS’ requirements, and also provide a fairer and more accurate analysis of the rule’s impact.</p>	<p>separate conclusion for each sector analyzed.</p> <p>L&amp;I’s decision not to reflect benefits in the SBEIS was neither arbitrary nor capricious, but compliant with both the law and the purpose of the SBEIS. The benefits were reflected, as required, in the BCD.</p>
3.03	<p>L&amp;I’s proposed steps to reduce the costs of the rule across the board as to all agricultural employers are illogical and contrary to the SBEIS statute, because they do nothing to address the supposed disproportionate impact but simply reduce the impact as to all employers with employee who are exposed to dangerous neurotoxins.</p> <p>L&amp;I has proposed mitigation, including weakening protections for farmworkers, across all sectors—even sectors that will not experience a disproportionate impact from this rule—in contravention to Washington law. The SBEIS statute states:</p> <p><i>Based upon the extent of disproportionate impact on small business identified in the statement prepared under RCW 19.85.040, the agency shall, where legal and feasible in meeting the stated objectives of the statutes upon which the rule is based, reduce costs imposed by the rule on small businesses.</i></p> <p>RCW 19.85.030 (emphasis added). The SBEIS statute’s plain language</p>	<p>The mitigation measures in the rule <i>do</i> provide greater relief for small businesses than large, relieving the disproportionate impact. RCW 19.85.030(2)(d) specifically authorizes L &amp; I to mitigate disproportionate impacts by delaying the compliance time tables.</p> <p>The law neither requires L&amp;I to nor prohibits L&amp;I from presuming disproportionate impact and from providing the same mitigations provided to small employers in industries where a disproportionate impact is found and to small employers in those industries where no such impact is found. L&amp;I’s ability to mitigate requirements in the ways described in the rule proposal is not a result of any grant of authority by the Regulatory Fairness Act. All intended mitigations are within L&amp;I’s authority and therefore cannot be “conditioned” by the RFA.</p> <p>The commenter appears to criticize L&amp;I for welcoming additional suggestions for potential mitigation. The openness to such suggestions is central to the participatory process required and encouraged by the Administrative Procedure</p>

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	<p>conditions L&amp;I's ability to implement mitigation “[b]ased upon the extent of disproportionate impact...” <u>Id.</u> However, in the SBEIS, L&amp;I decided to “mitigate[] impacts across all sectors, in spite of the absence of a disproportionate impact in some cases.” <u>SBEIS</u>, 16 n.7. In addition to mitigation that L&amp;I designed to address the disproportionate impacts of the rule, the agency also “appl[ied] [further] mitigation across all three sectors, regardless of whether a disproportionate impact [was] found in each case.” <u>SBEIS</u>, 17. L&amp;I then added an additional potential layer of mitigation by stating that the agency “welcome[d] any suggestions for further mitigations of the rule’s disproportionate impact...” <u>SBEIS</u>, 19.</p> <p>L&amp;I’s overzealous application of mitigation is wholly out of proportion to any potential disproportionate impact. L&amp;I concluded there might be disproportionate impacts for small businesses in the “Other Growers” category during the first year of the rule’s implementation, but not after the second year, and for professional applicators in the second year. <u>SBEIS</u>, 16.</p>	<p>Act and other statutes.</p>
3.04	<p>L&amp;I states, without providing any rationale, that “a disproportionate impact on small business was considered to exist if the estimated cost per covered pesticide handler was more than 10 percent greater for small business than for the largest 10 percent of business in the same industrial sector.” <u>SBEIS</u>, 16 n.17.</p> <p>• • •</p>	<p>The 10 percent threshold was selected in advance of the analysis based on a reasoned consideration of the relationship between small and large growers in agriculture. The commenter presumes that if L&amp;I has ever used a different standard then 1) both standards cannot be acceptable within their context and 2) the previous (and higher) standard is necessarily the correct one. L&amp;I disagrees with both assumptions and notes that the commenter does not provide any reason to suggest that a greater than 10 percent disparity represents a disproportionate impact in the context of this rule.</p>

SBEIS, 16. L&I’s disproportionate impact determination is ultimately based on professional applicators having a higher per handler costs of 15.4% in the second year. SBEIS, 16-17. However, this determination is inconsistent with L&I’s determination in other Small Business Economic Impact Statements. In one such statement, L&I concluded that a “12 % higher [cost per employee] for small employers relative to large employers [is not] indicative of [a] disproportionate impact.” L&I, Small Business Economic Impact Statement-General Traffic

In addition, it is not clear to which previous document the comment refers. The SBEIS on the department’s 2002 proposal to increase requirements related to traffic safety on construction sites concluded that there would be a disproportionate impact requiring mitigation.

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3.05	<p>Safety Requirement for Construction Sites, 14 (2002). Standing alone, this contradiction invalidates L&amp;I's disproportionate impacts determination in this rule.</p> <p>L&amp;I arbitrarily failed to adjust numerous unrealistically high cost estimates. L&amp;I also arbitrarily failed in the SBEIS to correct the artificially inflated cost estimates for this rule. The agency used information from growers who have a bias to inflate cost estimates. These growers gave inconsistent answers that benefited their positions in response to survey questions.</p> <p><u>SBEIS</u>, at 5 and 8, and Kirk Mayer, Email accompanying "Spray Related Activities" (Sent to Groepker Reinhold off L&amp;I on Friday, May 30, 2003).</p> <p>L&amp;I accepted this biased data without correction and presumed higher costs when confronted with inconsistencies.</p> <p>When addressing the same set of conditions in the SBEIS for General Traffic Safety Requirements for Construction Sites, L&amp;I used statistical techniques to correct inaccuracies that inflated cost estimates. L&amp;I, <u>SBEIS</u> for General Traffic Safety Requirements for Construction Sites, 8-10 (2002).</p> <p>However, in this rule, L&amp;I arbitrarily refused to apply the same techniques to help correct cost overestimates and, instead, applied the high-cost estimates. <u>SBEIS</u>, 8. L&amp;I's arbitrary decision not to correct for inaccuracies invalidates the agency's cost estimates. At a minimum, L&amp;I should eliminate the mitigations that weaken of protections for human health to compensate for the agency's failure to correct the cost overestimates.</p>	<p>The grower survey data used by L&amp;I to estimate many costs clearly represents the best available evidence of costs. The commenter criticizes L&amp;I for using the costs without correction, but does not provide any specific basis for the need to correct the costs. The commenter appears to assume that because growers have reason to inflate costs, they have necessarily done so. The commenter criticizes L&amp;I for not correcting "the cost overestimates" without indicating a single cost that has been overestimated or any specific reason that a cost may have been overestimated in light of the methodology and survey questions used. Indeed, the same payroll benefit cost estimates by Kirk Mayer, found in the May 30, 2003 e-mail (and adjusted somewhat for the final BCD), were criticized as too low by another grower organization.</p> <p>Because many of the unit costs were estimated separately from the grower survey (for example, the costs of the various medical procedures were based on contacts with medical providers and other available information). However, it was not necessary to apply general statistical techniques to correct for the inaccuracies that the commenter believes are present. In some cases (and as discussed in both the SBEIS and BCD) minor modifications to the data were necessary to correct for apparent errors made by the responders.</p> <p>In any case, it is not clear how the alleged overestimate of costs to both large and small growers could justify a refusal to mitigate, to the degree possible, the disproportionate impacts identified in the analysis the department was required to complete to comply with the RFA. And the department does not believe that any of the proposed mitigations weaken protection for human health, nor did the comment provide any specific concerns about the mitigations reflected in the SBEIS (for example, it is clear that providing growers with sample forms or with lists of providers who are willing to provide medical monitoring would in no way weaken protection of workers).</p>

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3.06	<p>The SBEIS statute does not allow L&amp;I to adopt mitigation measures that undercut the mandate of WISHA or the Supreme Court's Holding in <u>Rios</u>. L&amp;I's Small Business Economic Impact Statement (SBEIS) identifies no significant disproportionate impacts on small business that require significant mitigation.</p> <p>• • •</p>	<p>L&amp;I agrees that it cannot adopt mitigation measures that violate WISHA, and L&amp;I has not done so in this rulemaking. Rather, the mitigation measures are consistent with WISHA and with the RFA.</p>
3.07	<p>In any event, the SBEIS statute does not allow L&amp;I to adopt mitigation measures that undercut the mandate of WISHA or the Supreme Court's holding in <u>Rios</u>. The SBEIS statute states that if, or to the extent that, a disproportionate impact is identified in the SBEIS, “the agency shall, <u>where legal and feasible in meeting the stated objectives of the statutes upon which the rule is based</u>, reduce the costs imposed on small businesses.” RCW 19.85.030(3) (emphasis added). Because WISHA and the Supreme Court's holding in <u>Rios</u> require L&amp;I to adopt a ChE rule to protect farm pesticide handlers from being poisoned by toxic pesticides, the SBEIS statute does not allow L&amp;I to adopt any mitigation measures that prevent these WISHA and Supreme Court mandates from being met.</p>	<p>The RFA requires L&amp;I to consider the impact on revenues, not on net income. While it is obviously true that smaller farms will be likely to have less revenue than large farms, it is also true that their compliance costs are likely to be below the average. For example, a farm with two handlers that used OPs but below the 30-hour threshold would pay a total of less than \$15 yearly to comply with the rule. The department remains convinced that the rule would not have a discernible impact on industry revenue, and only a minimal impact on overall costs. The present economic difficulties faced by certain sectors of the agriculture industry do not invalidate the agency's determination that the rule is economically feasible, discussed in more detail in the main body of the CES, and that the probable benefits will exceed the probable costs, as discussed in more detail in the BCD.</p> <p>The last statement in the Small Business Economic Impact statement summing up the impacts of this rule on “affected industry sectors” is seriously flawed. That statement states “...the proposed rule’s impacts, when compared to a 2001 annual crop value in the affected industry sectors of more than \$3.7 billion, are likely to be minimal.” (Note: quoted comment footnoted to the WA Agricultural Statistics Service, 2002 Annual Bulletin.) That statement is assuming that an extra \$2.8 million dollar expense will not significantly impact the \$3.7 billion industry.</p> <p>It is critical to recognize that the \$3.7 billion is not net income to the grower. That number is farm gate value of the affected crops of which you need to subtract expenses to get to the real impacts of an extra \$2.8 million dollar expense.</p> <p>The number \$3.7 billion comes from Washington Agriculture Statistics</p>

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	<p>Service, 2002 Annual Bulletin. It should be noted that in that same report on page 11, it notes that approximately 62% of the farms in Washington State sold less than \$10,000 in agricultural products. Adding, a per small business firm cost of \$966 (\$466 per handler) is a significant cost.</p> <p>Tree fruit growers have experienced a tremendous amount of economic hardships in the past ten years. Production and regulatory costs have increased at a rate that exceeds the sales price for their product. Statistics etc. show that the industry is beginning to show the signs of losing ground to the ever increasing production and regulatory costs. See the list of indicators regarding grower economic health below.</p> <p>Tree Fruit Grower numbers in Washington State declined by approximately, 400 orchardists in the period between 1992 and 1997, (USDA 1997 Census). That downward trend has not been reversed and continues today.</p> <p>The Washington Growers ClearingHouse grower membership has dropped from 2,800 to approximately 2,200 in the last two years.</p> <p>Some Clearing House grower members have begun investigating potential orchard sites in Chile, Argentina, Mexico and Russia, etc.</p> <p>Despite the fact that Washington states is the number one producer of tree fruits in the United States, Washington state marketing firms have begun (in the last two years) to import and market tree fruit from other countries.</p> <p>Increasing numbers of orchardists are recommending that their college bound children not seek an agricultural degree or if they do, to have a second major. That the orchard may not be available when they graduate.</p> <p>WSU agricultural enrollment has plummeted.</p> <p>The Wenatchee Valley College tree fruit production program enrollment has also decreased significantly resulting agricultural related program &amp; staff reductions.</p> <p>One suicide occurred in the Yakima area that was related to industry economics.</p> <p>WSU has created a new program "Farm Family support Network. The network's goal is to assist farm families who are experiencing business and family stress.</p> <p>The ClearingHouse and other industry associations worked with county</p>	

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	<p>health officials to develop information for the industry to aid in recognizing suicide symptoms.</p> <p>Approximately, 31,000 acres of Washington apple acreage has been removed in the last five years. (Source: Wenatchee Valley Traffic Assn./Yakima Valley Growers &amp; Shippers Assn.) (Note: Such tree removal has not occurred in the past except during the Depression years.)</p> <p>During the past three years several thousand acres of tree fruit were abandoned or not farmed.</p> <p>Abandoned orchard pest control became a threat to the industry resulting in WSDA setting aside and providing emergency funds to aid county pest control boards in removing or spraying abandoned orchards.</p> <p>Several Fruit Grower Cooperatives have gone bankrupt or gone out of business during the past five years.</p> <p>DOLE Fruit Company, who purchased several packing facilities and orchards in the Wenatchee area and announced they planned on becoming a major player in the Washington Fruit Industry suddenly decided that the economic incentive was lacking and sold all their Washington orchard and warehouse holdings.</p> <p>Banking institutions recognizing the increased risk associated with funding orchard operations cut back the orchard portion in their respective loan portfolios.</p> <p>Banks shifted from securing orchard loans shifted to emphasizing cash flow security.</p> <p>In some cases interest rates were raised as high as 13% in the year 2000 &amp; 2001.</p>	<p>Growers Credit Corporation who provided loans solely to Washington orchards closed its doors due to lack of funds.</p> <p>Columbia Legal Services recognizing the financial problems most growers were facing, began the practice of placing a lien on the orchard property of those growers they were suing.</p> <p>Growers questioned their funding on the number one commodity promotional commission in the United States, the Washington Apple Commission. Growers sued to force the significant downsizing of the WAC.</p>

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	<p>Reducing the assessment by 85%.</p> <p>According to USDA, (Capitol Press, Aug. 22, 2003) a recent court case involving spray buffers is expected to cost agricultural producers in Washington State in excess of \$100 million a year.</p> <p>Unemployment and industrial insurance rates paid by growers increased significantly during the past three years, and increases are currently proposed for 2004.</p> <p>The Washington agricultural minimum wage rate is the highest in the country.</p> <p>Due to the increased labor related costs Washington tree fruit growers have been working to modify their orchard operations so that less labor is needed. The number of orchard related jobs have continued to decline since their peak in 1998. The total annual average orchard employment dropped from 31,125 in 2000 to 28,398 in 2001. (Source; WA. Employment Security Industry Employment &amp; Wages Annual Averages [www.wa.gov/esd/lmea.]).</p> <p>The Washington Tree Fruit Research Commission is pursuing ways to speed up the process of incorporating technology in the industry in an effort to reduce production costs by 30% by 2010. See "Technology Road Map" at <a href="http://www.treefruitresearch.com">www.treefruitresearch.com</a> &lt;<a href="http://www.treefruitresearch.com">http://www.treefruitresearch.com</a>&gt;</p> <p>All these factors should be included in the small business economic impact statement to determine the impacts of increased costs to family farmers in Washington State.</p>	<p>Last it should be noted that while 62% of the farmers in Washington State sold below \$10,000 worth of product the average farmworker earned \$14,531. Which means more than fifty percent of the farmworkers earned more than 62% of the farmers. (Page 20, Agricultural Workforce in Washington State, 2001, Wa. Employment Security.)</p> <p>There was no feasibility analysis.</p>

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	<p>One of the requirements is that the regulation be feasible. The department fulfilled this requirement by comparing the revenue of the industry, which it places at \$3.7 billion, with the projected costs of complying with the proposed regulation (29). A more meaningful analysis would be to determine the net income or profit of the industry when determining whether a new regulation is feasible. Economic data from USDA demonstrates that the apple industry is not profitable. In fact, the industry was awarded over \$100 million in 2000 because of market losses; i.e. the cost of production exceeded the revenue.</p> <p>Farm Bureau requests the feasibility analysis be corrected to reflect economic reality - labor-intensive agriculture in this state is in a deep recession. Readily available employment figures and the decreasing numbers of acres being planted demonstrate this basic tenet. Farm Bureau requests a feasibility statement that adequately reflects the net income and the ability of the industry to undertake a costly new regulation, as was explained in detail by the Court in <i>Rios</i>.</p>	<p>The department did not describe its reference to the rule's impact on the overall revenue of the industry as a determination that the rule was feasible. The main body of the CES contains the discussion of the department's determination that the rule is feasible.</p> <p>It is not clear what further steps the commenter believes are required by the court's analysis in <i>Rios</i>. To the contrary, the court in <i>Rios</i> concluded that in this "extraordinary circumstance" the feasibility issue had essentially already been addressed: "Because the Department had already invested its resources in studying cholinesterase-inhibiting pesticides and because the report of its own team of technical experts had, in light of the most current research, deemed a monitoring program both necessary and doable, the Department's 1997 denial of the pesticide handlers' request was 'unreasonable and taken without regard to the attending facts or circumstances.'" Rather than relying upon this finding by the <i>Rios</i> court, however, the department has made a fresh determination of feasibility, based on the current record.</p>
3.08	<p><u>Table 1: Central Cost Estimates by Industry Sector</u></p> <p>Orchardists category: I had a difficult time understanding some of the economic data, especially related to the total cost, on page 2 for a small orchardist (year one) is shown as \$169 per handler. However, using the costs provided in the Impact statement: The doctors fee, one base line lab test cost and the evaluation of a single lab test add up to \$205. (\$112, \$55, \$38.) In most cases the test will</p>	<p>The "per handler" costs are calculated by dividing the total costs by the number of handlers using OPs or carbamates. Not all such handlers require medical monitoring. The average cost per monitored handler is higher, and varies considerably based on the number of periodic tests that will be required (although it is true that if monitoring is required for a handler at least two tests will be required).</p>

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	<p>need to be done twice. (Under the rule a base line test is required and a second test 30 days later if the threshold has been met, whether further exposure occurs after the 30 days or not.) The cost of transportation, wages during transportation and the time in the doctors waiting room, plus the clinical evaluation and clerical work to draft a letter to notify the employer, employer record keeping and employee training etc. need to be added. It also should be noted that the foreman or employer will most likely have to drive the employee to the doctor. The second year per handler cost of \$466 is also low but more accurate.</p> <p>...it also not appropriate to assume that L &amp; I will be able to negotiate a reduced cost on behalf of employers. The full rate should be used in all levels of the analysis. Nor is there a small orchardist cost of hiring a temporary individual to the place of the replacement worker.</p>	<p>The department remains convinced that the most likely scenario will involve a reduced rate for laboratory analysis, both because the department believes it can help negotiate such a rate and because the economies of scale will make reductions likely. Even when the “full rate” is reflected, as it is by the high cost analysis in the SBEIS and the BCD, the resulting conclusions remain unchanged.</p> <p>The cost estimates in the BCD have been adjusted to reflect the training costs involved in replacement, reflected by an estimate of an additional \$2 per hour (in training costs, lost productivity due to limited experience, etc.).</p>
3.09	<p>Wage Costs page 13. “The (central) estimate also assumes the reported reassignment jobs have full value to the employer, so that the cost to the employer will be accurately reflected by an estimated \$2 per hour in additional wages to pay another worker to take on the higher level of duties normally performed by the pesticide handler.” It appears that the replacement worker cost analysis fails to add the cost of training/pesticide license cost etc. of the promoted replacement worker. In the case of the small orchardist it also fails to add the cost of locating, hiring and training a new “temporary” employee to fill the void left by the replacement worker (I-9’s, W-4’s) etc. While I recognize that job removal will be very rare, it should be noted that small orchardists, who may have one key employee, will have a very difficult time replacing that key employee, especially on a temporary basis. Despite the current high unemployment rate in most rural counties it is very difficult to find, and hire a qualified person in a timely manner.</p> <p>Failure to hire a replacement pesticide handler (applicator) in a timely manner can lead to pest related crop loss and/or in worst case scenario a quarantine for a single pest find.</p>	

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3.11	<p>Measuring impact to the farmer by comparing to the farm gate crop value is not relevant. The grower has to deduct his/her expenses from the farm gate value to get to their real income. (Using the \$3.7 million figure is like saying Washington State collects billions in tax revenue, so they can afford to increase expenses.) The fact is that 63% of all Washington farms had crops with a sales value of less than \$10,000*. Far too often government and labor advocates use crop value as an indicator of a grower's financial health and ability to pay. In recent years the net income to the farmer has been at record low levels and for far too many farmers non-existent. Note: See enclosed folder of economic data.</p>	<p>L&amp;I agrees. The RFA requires a consideration of industry revenue, but that does not necessarily reflect the impact on individual growers. Those are better described by the per business and per handler figure, but even those figures represent averages and there will be variations within the industry.</p>
3.12	<p>The department should bear full responsibility for the cost of all testing, research and data gathering during 2004 and 2005.</p>	<p>The WISHAct specifies that the cost of medical monitoring is an employer responsibility. However, L&amp;I will cover the costs of research and data gathering and will mitigate the testing costs to the extent possible using the \$378,000 legislative appropriation and any additional appropriations.</p>
3.13	<p>The cost. The cost to the agricultural industry, that this would definite impact our farmers. They will be the ones paying for this, the employers, the agricultural employers. And, again, we have singled out the agricultural industry within all of the industries that use these pesticides. And I do question that.</p> <p>The regulations already in Washington state, again, we can't have our folks picking up their cherry orchards and moving to Idaho. It's not that easy. But we do need to make sure and have as a goal and in perspective with our states agencies that regulations putting our farmers out of business are not proper regulations.</p> <p>... who's going to take responsibility for the economic impacts put on both small and large farms...?</p>	<p>As discussed in greater detail in the main body of the CES, the department has concluded that cholinesterase monitoring is economically feasible.</p> <p>The rule includes a mitigation measure, which applies to both small and large agricultural employers, through the phase-in approach to the medical monitoring. In addition, L&amp;I will cover the costs of research and data gathering and will mitigate the testing costs to the extent possible using the \$378,000 legislative appropriation and any additional appropriations.</p>

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	On the economic impact, I am not certain that we went far enough into identifying the results of that economic impact on the areas and on the people that may or may not be in effect at that time	
3.14	...it may not necessarily be the employer's responsibility for the cause of the employee's warranted drop in the cholinesterase levels.	The employer remains responsible for the safety of employee work practices at the job site. The department has concluded that a well-designed monitoring program relying upon pre-exposure employee baselines will avoid "false positives" based on pre-existing conditions or other employee-specific factors.
4.0	<b>Benefit analyses</b>	
4.01	Farm Bureau has requested a cost benefit analysis. It has not been provided. We request that the cost benefit data be provided to all stakeholders, and the hearing and comment period be re-opened so that people will have the opportunity to comment on L&I's cost benefit analysis. Since we have not received any cost benefit analysis, we can only comment on the small business economic impact statement (SBEIS) and speculate about the cost benefit figures.	The benefit cost determination (BCD), also known as a cost benefit analysis, has been completed prior to a decision on the rule, as required by law. In addition, a draft of the BCD was circulated for additional public comment.
	The projected medical removal estimates are not supported by data. It appears that the 4.8% high estimate was taken from 1985 data. This is pre-PPE and at a time when much larger quantities of more toxic formulations were being used. Please explain the basis for the 4.6% medical removal in light of the overwhelming data after implementation of PPE that indicates few if any exposures.	The discussion of appropriate removal rates is addressed in the specific response to comments from the Washington Farm Bureau.
	A more accurate central estimate for medical removal rate is 0.5%, with 0% as the low estimate and 1% as the high estimate.	As discussed in more detail in the specific response to comments from the Washington Farm Bureau, the department disagrees with the belief that there will be any discernible number of "false positives" when abnormal test results are reported. The belief that such false positives will occur is based on a misunderstanding of the research data and its relationship to the rule. The "investigation" required by the rule is not an investigation to determine whether depression occurred but to determine, when depression is reported, whether work practices need to be corrected. This is part of an employer's ongoing responsibility to ensure safe work practices and appropriate PPE and engineering

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	<p>abnormal results that can logically be anticipated an analysis will show that costs exceed benefits. Once again, we would like the opportunity to officially comment on a preliminary cost/benefit analysis.</p> <p>The department has underestimated the number of tests that will be required each year. L&amp;I used a telephone survey to determine the numbers of workers who are applying pesticides. Naturally, in a telephone survey with a person who is under contract with the department, farmers will under report the quantity of pesticides being used. L&amp;I should obtain data from chemical companies to determine how much of each chemical is sold each year, and use this data to modify the survey results.</p> <p>.....</p> <p>.....</p> <p>.....</p>	<p>controls are both available to and used by employees.</p> <p>The survey did not ask for the quantity of pesticides being used, but for the number of employees who would be likely to be exposed above certain thresholds. Obtaining the quantity of pesticides used, from whatever source, would not allow the department to estimate the number of affected employees because it would not answer questions as to whether employees were handling the pesticides and how many employees were handling the pesticides at levels above the threshold in the rule. The department concluded that the best method to obtain such information was an employer survey, and the survey results certainly represent the best information available in the records regarding this issue.</p> <p>The Gilmore Research staff who conducted the survey used a script that included the following statements:</p> <p>“Hello, I am calling from Gilmore Research and we are conducting a phone survey for a workplace safety and health rule that is being proposed by the Department of Labor and Industries. This is the result of a Supreme Court ruling. This survey is being done to determine the possible economic impact of this rule on affected employers.”</p> <p>.....</p> <p>.....</p> <p>.....</p>
	<p>There is no evidence that the department considered that survey participant's may underestimate that amount of chemicals they use. This is a natural response from a person to a telephone survey. Naturally, there is a stigma to using chemicals, and very few people will admit the use of chemicals to a telephone survey.</p> <p>.....</p> <p>.....</p> <p>.....</p>	<p>A telephone survey is a less optimal way to determine usage of chemicals. Farm Bureau requests that the department contact chemical dealers and request numbers of customers that utilize the target chemicals. Combining this date with the survey results would possibly produce different estimates for the number of workers and farms that will be impacted.</p> <p>.....</p> <p>.....</p> <p>.....</p>
		<p>“The information in this survey will help L&amp;I make decisions regarding this rule proposal. Your identity will be kept anonymous and the specific answers you give will not be associated with your name when provided to the department.”</p> <p>The commenter suggests that growers set out to intentionally mislead the department as to the extent of the rule's likely effect on them even when they had been told that the information would be used to make decisions about the possible economic impact of the rule. Other commenters have suggested that the responses</p>

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	<p>The survey data was too small and should be supplemented. L&amp;J attempted to survey 524 growers, but actually only completed interviews with 134</p>	<p>As is normal practice with surveys, Gilmore Research attempted to contact more employers than needed to complete a statistically valid survey, in order to ensure that sufficient data would be available even if a number of employers could not be contacted. The commenter does not explain why the number of interviews completed was not sufficient.</p>
	<p>Finally, the workers' compensation premium rate in the SBEIS is used as 3.72%. We believe that the workers' comp premium rates are over 5% of payroll, based on our information regarding the hourly rates, typical being paid, and the expected rate increases. Please check with the workers' comp division and determine if the 3.72% figure must be corrected.</p>	<p>The rate quoted in the comment refers to the 2003 base industrial insurance premium rate in one of the affected industries. It is a common misconception that the base rate is the average rate. As discussed in the BCD, the base rate does not actually reflect the average rate paid (the average employer actually has an industrial insurance experience factor below 1.0000), and it includes premiums paid by workers as well as by growers. However, the figures used in the BCD were adjusted to reflect the recently adopted rate increases.</p>
	<p>In addition to the quantitative costs and benefits, the department must measure the qualitative costs and benefits. There is no such thing as a "qualitative cost benefit analysis." The term is a legislative creation that directs the agency to consider qualitative factors.</p> <p>The principal qualitative cost is the huge disruption of workers privacy. No one likes to be forced to give a venous blood sample. Repeating the process</p>	<p>As required by the APA in RCW 34.05.328(1)(c), the agency has considered both qualitative and quantitative factors in the BCD. While the commenter may not like the term, the department agrees that the law requires consideration of qualitative factors.</p> <p>Under the proposal and the rule as adopted, no worker would be forced to give a blood sample.</p>

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	<p>five times a year is a huge qualitative cost. In addition, workers with low ChE levels will be subjected to further intrusions. It is documented that use of drugs or alcohol can depress ChE levels. A low ChE test will necessitate an inquiry into a person's private life. This inquiry will be particularly stressful for a section of the population that may not be legally documented to work in this country. Without a clear and quantitative benefit, it is not wise to place this imposition on these workers.</p> <p>The principal qualitative benefit would be to identify improper workplace safety procedures or improper use of PPE before a worker is exposed. This would be a great result, unfortunately, the data does not show evidence that any appreciable numbers of workers are suffering from exposure to these chemicals at present.</p> <p>Another qualitative benefit would be to prevent a permanent injury. There is no credible scientific evidence suggesting that low-level exposure, over time, leads to any permanent condition.</p> <p>Finally, it is noteworthy to repeat that this proposed regulation cannot prevent an acute exposure due to an accidental spill. Proper training and utilization of personal protective equipment can prevent such an exposure. The qualitative costs resulting from encroachment on privacy, fear from the large number of abnormal results that turn out to be false, and the incumbent prying of medical investigators outweigh the qualitative benefit as a diagnostic tool to employers and workers in a relatively small number of cases.</p>	<p>The risk of pesticide exposure and poisoning is discussed in more detail in the main body of the CES and in the detailed response to the Washington Farm Bureau comments.</p> <p>Monitoring will not directly prevent spills, but monitoring can be used to identify spills (and the resulting over-exposures) that go unreported, and can also be used to identify a pattern of breakdowns in work practices and PPE use. By doing so, monitoring can be expected to prevent some spills and also to make it more likely that proper PPE is being used in the event of a spill.</p>
	<p>It is unclear how much employee turnover is assumed in the SBEIS. Please provide the estimate and the method for determining this figure.</p>	<p>As described in the assumptions section of the SBEIS (and in both the review draft and final BCD), the central estimate assumes that 50 percent of these employees will return in the second year, based on consistent descriptions of these</p>

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4.02	<p>L&amp;I's cost-benefit analysis must consider all of the significant benefits of the ChE rule, including the benefits to workers and their families, the broader social and environmental benefits, and the benefits to employers.</p> <p>In its cost-benefit analysis, L&amp;I must consider all of the significant benefits of the ChE rule, and not simply the implementation costs. The benefits of the rule include the health protection benefits to handlers and their families, the broader social and environmental benefits, and the economic benefits to employers that will result from having healthier and more productive workers.</p> <p>L&amp;I considered these same types of benefits (i.e., health benefits to workers, broader social benefits, and economic benefits to employers) in its cost-benefit analysis for the ergonomics rule. See L&amp;I's Cost-Benefit Analysis of Ergonomics Standard (May 2000), page 1 ("the benefits to society significantly outweigh the costs of compliance"); <u>id.</u>, pages 1-2 ("those employees afflicted with a serious WMSD [work-related musculoskeletal disorder] experience reductions in long-term earning potential and family stability"); <u>id.</u>, page 2 ("[T]here are sizable indirect employer costs associated with WMSDs. The indirect costs, that are the consequence of WMSDs, are borne by the employer in the form of higher absenteeism, turnover and replacement training costs as well as lower productivity").</p> <p>All of these same benefits will result from the ChE rule, and they should all be taken into account by L&amp;I in its cost-benefit analysis. As the Washington Growers League (one of the stakeholders representing employers in this rulemaking) stated in a 1996 article:</p> <p style="padding-left: 2em;">Cholinesterase testing for farm workers helps reduce liability, increases safety awareness, exposes problems with chemical handling and use of personal protective equipment, and eases the minds of both workers and</p>	<p>workers in stakeholder and public meetings as being "highly valued" and "stable" members of the employer's workforce. The low estimate assumes that 75 percent of employees will be returning in the second year. The high estimate assumes that only 25 percent of employees will return in the second year.</p> <p>The department's final BCD includes further discussion of these benefits. However, the department considers it feasible for growers to continue to use covered pesticides and has not identified "environmental benefits" as a benefit under the rule (nor does the department consider reduced pesticide use to be a cost under the rule).</p>

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4.03	<p>Agricultural employers.</p> <p><u>Agricultural and Environmental News</u> (October 1996), page 11 (quoting Phil Hull of the Washington Growers League, copy enclosed). We agree that the ChE rule will have all of these significant benefits and more.</p> <p><i>A. Benefits to Human Health</i></p> <p>A strong medical monitoring rule can help:</p> <ul style="list-style-type: none"> <li>◆ Alleviate sensory and motor nerve impairment of workers after long-term, <u>low-level exposure</u> to organophosphate pesticides.</li> <li>◆ Reduce incidents of depression and other profound mental and psychological impacts.</li> <li>◆ Decrease incidents of retinal degeneration, which is a leading cause of visual impairment in older adults.</li> <li>◆ Diminish the risk of permanent adverse impacts on the nervous system from chronic exposure to low levels of organophosphate pesticides.</li> <li>◆ Lessen the potential for spontaneous abortions, birth defects, and some of the most common forms of genetic syndromes.</li> <li>◆ Reduce incidents of exposure to neurotoxins to children and family members of farmworkers from take-home exposures. . . . Reductions in exposure to children and family members could occur when workers are medically removed from activities that expose them to pesticides. Reducing exposure to children could incur particularly high benefits given the National Academy of Sciences acknowledgement that “[c]ertain populations of children may be more sensitive to the effects of pesticides because of physiological and biochemical factors...include[ing] exposure through farm work or parental occupational exposure and low socioeconomic status.”</li> </ul>	<p>The department has provided increased discussion of some of these benefits in the final BCD.</p>

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4.04	<ul style="list-style-type: none"> <li>◆ Fill data gaps in the collection of health effects information related to numerous neurological impacts implicated by exposure to organophosphorus pesticides.</li> </ul> <p><i>B. Benefits to Society</i> In addition to the social benefits described above, a medical monitoring rule could help:</p> <ul style="list-style-type: none"> <li>◆ Create a critical component of a much-needed regional and national system for collecting and analyzing pesticide exposure data, especially for some of the most dangerous pesticides still used by agriculture.</li> <li>◆ Promote the use of alternative to dangerous pesticides, which will create multiple benefits for growers and workers. Ensuring that growers internalize the costs of using dangerous products will create incentives to use established and successful agricultural practices, such as organic farming. Organic farming promotes worker safety; increases labor availability relative to growers who use dangerous pesticides; creates healthy, productive soil; controls major pests (e.g. codling moths) while helping to restore natural predators for numerous other pests; and reduces business costs and increase profits.</li> <li>◆ Create incentives to use alternatives to pesticides will also benefit children and the families of farmworkers. There is also a wealth of information from other sources that describe troubling data on children's exposures from pesticide drift, take-home exposures, and other factors.</li> </ul> <p><i>Benefits to Business</i> In addition to the benefits to business described in the first section, a medical monitoring rule can help to:</p> <ul style="list-style-type: none"> <li>◆ Create incentives to switch to organic agriculture, which promotes international competitiveness against growers in other nations who are increasing their production of organic crops and provides profitable and high-quality produce for rapidly expanding segments of the domestic and</li> </ul>	<p>The department considers the relative value of making information available outside Washington state to be low in the context of this rulemaking, which requires action by Washington state employers and should be justified in the state context; however, the value to Washington employers, workers, and occupational and public health agencies is meaningful.</p> <p>The department has concluded that use of alternatives to OPs should not be considered as either a cost or a benefit of the rule.</p>
4.05		<p>The department has concluded that use of alternatives to OPs should not be considered either a cost or a benefit of the rule.</p>

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4.06	<p><i>Environmental Benefits</i>            A medical monitoring rule would also create incentives to use organic agriculture. The use of organic agriculture would help create multiple environmental benefits.</p>	<p>The department has concluded that use of alternatives to OPs should not be considered either a cost or a benefit of the rule.</p>
4.07	<p>This proposal comes at a time when the overall business climate in Washington State is very poor. Legislators and staff from the Governor's office are currently meeting with business representatives to identify issues associated with our current economic crisis. One of the main issues identified this week in Yakima at a Legislative Trade and Economic Development Committee meeting chaired by Representative Mary Skinner, were runaway agency regulations. Washington is known as a liberal, tax and spend state. The proposal is a prime example of an agency action that increases burdens on business without justification.</p>	<p>The department has considered the entire record, in light of its statutory mandates, and has concluded that the rule is both necessary and feasible.</p>
5.0	<p><b>BCD – comments received 10/15 through 10/31</b></p> <p>L&amp;I has failed to consider the reduced pesticide exposure that will result from the shift in employers' pesticide application practices. In its discussion of the <u>costs</u> of the ChE rule, the draft cost-benefit analysis cites L&amp;I's survey results showing that a large proportion of employers will respond to the rule by reducing the number of hours that each pesticide handler is exposed to the covered pesticides in any 30 day period. See Draft Cost-Benefit Analysis, p. 14 &amp; Table 2. L&amp;I concluded that the costs of this shift in pesticide application practices are "essentially identical to the cost of complying without any change in work assignments." But L&amp;I failed to consider the significant <u>benefits</u> to pesticide handlers and their families of this shift in pesticide application practices. Some of the employers surveyed said they will discontinue pesticide use entirely as a result of the ChE rule. <i>Id.</i>, Table 2 (in the "other growers" category, 5% of small businesses and 8% of the largest businesses said they will discontinue pesticide use). Even more importantly, a large proportion of all employers surveyed said they will respond to the rule by keeping the number of hours that each handler is exposed to the covered pesticides below threshold levels. <i>Id.</i> (in the</p>	<p>The department has concluded that use of alternatives to OPs should not be considered either a cost or a benefit of the rule. However, the final BCD does take note of the reduction of concentrated exposure to certain workers, as suggested by the survey.</p>

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	<p>"professional applicators" category, 62% of small businesses and 100% of the largest businesses said they will respond by keeping exposure hours below the threshold levels; in the "orchardists" category the percentages were 49% and 61%; and in the "other growers" category the percentages were 33% and 75%.</p> <p>Because the risk and incidence of pesticide-related illness are lower when exposure is lower (which is the basis for the threshold), these changes in pesticide application practices and the resulting reduction in exposure are another significant benefit of the rule. L&amp;I has overlooked this benefit and should include it in the final cost-benefit analysis.</p>	
5.02	<p>L&amp;I has failed to consider or not given sufficient weight to the rule's significant unquantified and qualitative benefits to pesticide handlers and their families.</p> <p>In the Cost-Benefit Analysis of the Ergonomics Standard, L&amp;I discussed the unquantified and qualitative benefits of that rule at length. L&amp;I stated for example:</p> <p style="padding-left: 20px;">While not used in our estimate of the total benefits of the proposed rule, it is important to acknowledge that the above costs [of work-related musculoskeletal disorders] are not an exhaustive account of all the costs borne by the worker, the worker's family and by society at large. These include household economic losses, [diminished] ability to perform family and social roles, impact on family relationships, depression, living/working with pain, impacts to disability and welfare systems, and loss of the worker's contribution to community life.</p> <p>Ergonomics Cost-Benefit Analysis (May 2000), p. 32. Similarly, under the heading "Qualitative Benefits of the Ergonomics Rule," L&amp;I stated:</p> <p style="padding-left: 20px;">A large amount of costs borne by workers could not be quantified in the cost-benefit analysis. Although these are real social losses, they could not be quantified and they are therefore excluded from the benefit to cost ratio. They include:</p>	<p>The final BCD includes increased discussion of many of these benefits.</p>

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	<ul style="list-style-type: none"> <li>• Household economic losses           <ul style="list-style-type: none"> <li>• Diminished ability to perform family and social roles</li> <li>• Impact on family relationships</li> <li>• Depression</li> <li>• Living/working in pain</li> <li>• Other financial losses</li> <li>• Impacts to disability and welfare systems</li> <li>• Lost community benefits . . .</li> </ul> </li> </ul> <p>It is clear to the Department that the qualitative economic and societal losses associated with WMSDs [work-related musculoskeletal disorders] are large and important, and although they are not included in the cost-benefit calculation, they should be valued as social benefits of the ergonomics rule.</p> <p><u>Id.</u>, pp. 52-53 (emphasis in the original).</p> <p>In contrast, in the draft cost-benefit analysis of the ChE rule L&amp;I has virtually ignored these crucial benefits. L&amp;I should discuss and value them in its final cost-benefit analysis.</p>	<p>One of the benefits of early removal is the prevention of illness, which is acknowledged in the final BCD, as it was in the draft. It is not clear, however, whether the rule will result in an overall reduction of health care costs (particularly since it might result in the appropriate treatment of some illnesses that currently go untreated). Therefore, the reduction of health care costs has not been identified as a significant benefit in its own right.</p>
5.03	<p>L&amp;I has failed to consider the health care costs avoided by removing pesticide handlers with depressed ChE levels from further exposure before they suffer pesticide-related illnesses.</p> <p>In analyzing the benefits of the ChE rule, L&amp;I has also failed to consider the health care costs avoided by removing pesticide handlers with depressed ChE levels from further exposure before they suffer pesticide-related illnesses. See Draft Cost-Benefit Analysis, pp. 5-10 (discussing other benefits but ignoring avoided health care costs). The savings of health care costs that would otherwise be incurred was another key benefit that L&amp;I identified in its analysis of the ergonomics rule. <u>See Ergonomics Cost-Benefit Analysis</u>, p. 34. It is an important benefit of the ChE rule as well, and should be included in the final cost-benefit analysis.</p>	<p>The implementation plan is addressed in the rule and discussed in the main body of the CES. It was not part of the draft BCD, nor was L&amp;I statutorily required to address the implementation and enforcement plan prior to the adoption and filing</p>
5.04	<p>L&amp;I must fully comply with RCW 34.05.328(3).</p> <p>For the ChE rule to succeed, L&amp;I must fully comply with its obligations under RCW 34.05.328(3). That provision requires L&amp;I to develop and file</p>	

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	<p>with the final rule a detailed implementation and enforcement plan explaining how L&amp;I intends to:</p> <ul style="list-style-type: none"> <li>(a) Implement and enforce the rule, including a description of the resources the agency intends to use;</li> <li>(b) Inform and educate affected persons about the rule;</li> <li>(C) Promote and assist voluntary compliance; and</li> <li>(d) Evaluate whether the rule achieves the purpose for which it was adopted, including, to the maximum extent possible, the use of interim milestones to assess progress and the use of objectively measurable outcomes.</li> </ul> <p>RCW 34.05.328(3)(a)-(d). Although the proposed ChE rule has a nominal "implementation plan" (WAC 296-307-14845), there is no reference to it in the draft cost-benefit analysis, and the proposed rule and the draft cost-benefit analysis both:</p> <ul style="list-style-type: none"> <li>• do not describe how L&amp;I intends to enforce the rule, contrary to RCW 34.05.328(3)(a);</li> <li>• do not describe what resources L&amp;I intends to use to enforce the rule, also contrary to RCW 34.05.328(3)(a);</li> <li>• do not describe how L&amp;I intends to promote and assist voluntary compliance with the rule, contrary to RCW 34.05.328(3)(C); and</li> <li>• do not describe in any detail how L&amp;I intends to evaluate whether the rule achieves the purpose for which it was adopted, contrary to RCW 34.05.328(3)(d).</li> </ul> <p>L&amp;I must revise and expand its implementation plan to cure these deficiencies. Otherwise it will be impossible to evaluate the rule's effectiveness or to assess progress towards "interim milestones" or "objectively measurable outcomes" as required under RCW 34.05.328(3)(d).</p>	<p>of the final rule. See, RCW 34.05.328.</p>
5.05	<p>I would also like to use this opportunity to share information which I received from Dr. Rupali Das of the California Department of Health Services. Attached is an email she sent to me in response to questions I sent her in October. (Attachment 1.)</p>	<p>Although Dr. Das' data is preliminary, the department has taken note of this information and previous conversations with Dr. Das regarding the relationship between her data and the value of cholinesterase monitoring.</p> <p>The department agrees with the commenter (and Dr. Das herself) regarding the</p>

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	<p>It is unfortunate that California did not have the foresight to adopt a strong tracking and mandatory reporting component as part of its cholinesterase monitoring rule 25 years ago. The difficulties they now have in analyzing the data comprehensively highlight the importance of including that component in our own rule.</p> <p>The data in the slide show which Dr. Das provided earlier this fall has some significant limitations. It is data which has been voluntarily submitted by a limited number of labs. Apparently, workplace data is mixed with non-workplace data; information from agricultural settings with information from other settings. Dr. Das has been limited in her ability to effectively evaluate depression levels because baselines were not reported by two of the labs involved. It would be inappropriate to draw conclusions from the data received to date from Dr. Das regarding percentages of tested workers with depressions which should trigger investigations and/or removals.</p> <p>While comprehensive tracking by the state government has unfortunately not been a feature of the California program, academic institutions did do large-scale data collection and analyses in the past there, as the rulemaking record shows. These analyses documented that high percentages of tested workers had been significantly exposed, warranting workplace investigations and/or removals.</p>	<p>limitations of the data available to Dr. Das and the value of more rigorous data tracking and analysis, which is reflected by the Washington rule.</p> <p>The department also agrees with the commenter (and Dr. Das) that current California data, after more than two decades of medical monitoring, cannot necessarily be expected to accurately reflect the risks in Washington in the absence of medical monitoring. The department has concluded that the combination of medical monitoring, working in combination with appropriate protective measures required by the Worker Protection Standard, is the most likely explanation for any reduction in California over-exposures if Dr. Das' final analysis does indeed conclude that a reduction has occurred. As a general regulatory principle, L&amp;I agrees that a well-established medical monitoring program can be expected to generate a small number of medical removals – the primary value of such monitoring is not simply to identify overexposures but to provide an added incentive to prevent them and to provide a mechanism for early intervention before medical removal levels are reached.</p> <p>Columbia Legal Services and others have submitted analyses of regulations in place at the time of those studies, pesticides used, and other factors. Some changes have occurred since those years, including restrictions on the use of ethyl parathion. By in large, however, conditions in Washington today are very similar to those in California at the time of the studies there. Organophosphates in use in California then continue to be used today in Washington on high percentages of the acres used for labor intensive crops and at comparable rates of application. Because California already had requirements in place in the late 1980s and early 1990s similar to the Worker Protection Standards now on the books in Washington State, the regulatory framework is similar. In fact, Washington continues to provide less</p>

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	<p>protection today than California did then, because L &amp;I has not yet mandated closed systems for mixing and loading.</p> <p>Dr. Das notes that in California “Anecdotally, there are probably less frequent and less severe cholinesterase poisonings now <b>because of the existence of the (monitoring) law.</b>” (Email response to question number 3. Emphasis added.) She specifically notes that a decrease in depressions does not demonstrate that monitoring is not needed. On the contrary, it demonstrates the value of monitoring. “It is highly likely that some workers are not mixing/loading/applying ChE inhibiting pesticides as often as they would be if the law did not exist (because they have to be in the monitoring program if they work with Class 1/2 pesticides&gt;6/30 days).” She also notes that depressions below legal thresholds may be clinically significant. There is a value to obtaining information on all depressions.</p>	<p>The department agrees that the BCD must take into account the specific statute being implemented, based on both the clear language of the Administrative Procedure Act and the legislative findings at the time it was adopted. Both the review draft and the final BCD explicitly acknowledge this legal mandate.</p>
5.06	<p>Legal Standard for the Benefit-Cost Determination</p> <p>As L&amp;I noted in the draft Benefit-Cost Determination (BCD), the Administrative Procedures Act (APA) requires that the BCD for a WISHA rule take into account the specific directives of the WISHA statute. RCW 34.05.328(1)(c) requires that before adopting a significant legislative rule as defined by subsection (5), an agency must:</p> <p style="padding-left: 2em;">Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and <i>the specific directives of the statute being implemented.</i></p> <p>Emphasis is added.</p> <p>The Legislature’s findings when it adopted this provision specifically mandate that the provision not be construed to weaken the protection afforded workers by WISHA:</p> <p style="padding-left: 2em;">The legislature finds that . . . [w]orkplace safety and health not be diminished, whether provided by constitution, by statute, or by rule.</p>	<p>In <i>Rios v. Department of Labor and Industries</i>, 145 Wn.2d 483, 499-500 (2002), the Washington Supreme Court specifically held that the APA cost-</p> <p>The BCD and the main body of the CES discuss the department’s determinations regarding these issues in more detail.</p>
5.07		

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	benefit analysis for a WISHA rule must apply the WISHA statutory directives: [T]he Department's analysis of economic feasibility cannot be limited by the distinction in the federal cases between cost-benefit analysis and cost effectiveness, <i>for our state's APA expressly requires a cost-benefit analysis.</i> n10 [footnote 10: "Before adopting a rule ... , an agency shall ... [d]etermine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs <i>and the specific directives of the statute being implemented.</i> " RCW 34.05.328(1)(c).] We likewise embrace the principle of cost effectiveness and acknowledge here that <i>the critical language in the general definition of safety and health standard -- "reasonably necessary, or appropriate" -- works in tandem with the economic feasibility analysis to set a limit on the adoption of feasible methods.</i> RCW 49.17.020(7). Applying the respirator hypothetical from ATMI, we conclude that the director has a duty under RCW 49.17.050(4) to continue adding "respirators" so long as the additions are feasible, but only up to the point where additional ones are no longer necessary to protect against the worker's "material impairment of health." See <i>ATMI</i> , 452 U.S. at 513 n.32; <i>Bldg. &amp; Const. Trades Dep't v. Brock</i> , 267 U.S. App. D.C. 308, 838 F.2d 1258, 1269 (D.C. Cir. 1988) (concluding that "it is [the Secretary's] duty to keep adding measures so long as they afford benefit and are feasible"). In effect, to outstrip what is "reasonably necessary" is to go beyond "the extent feasible." Clearly, whether the Department has fulfilled its mandatory duty under WISHA will depend upon whether the Department has properly exercised its discretion in making the feasibility analysis.	Emphasis added; footnote 9 omitted. Thus both the APA and Rios require that the BCD for a WISHA rule be based on: 1) whether the standard is reasonably necessary or appropriate,

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5.08	<p>under RCW 49.17.020(7); and 2) whether the standard most adequately assures, to the extent feasible, that no worker suffer material impairment of health, under RCW 49.17.050(4).</p> <p>In summary, the effects of overexposure to cholinesterase-inhibiting pesticides are extremely serious and often long-term, potentially even permanent. Farm workers can experience these effects even with exposures that do not result in immediately apparent acute symptoms. As the TAG report found, the benefits of cholinesterase monitoring include protecting workers from developing chronic, long-term effects, in addition to preventing acute poisoning. Monitoring is essential to protect farm workers from serious health problems before they develop.</p>	<p>The department's determination that there is a significant risk is discussed in the main body of the CES and the relative costs and benefits are discussed in the BCD.</p>
5.09	<p>L&amp;I Should Consider the Following Evidence of Appropriateness and Feasibility of Cholinesterase Monitoring.</p> <p>In the <i>Rios</i> litigation, Dr. Michael O'Malley testified about his study of cholinesterase monitoring and his experience with the California monitoring program. Dr. O'Malley is an associate clinical professor in the Division of Occupational and Environmental Medicine at the University of California at Davis. He has treated farm workers for pesticide overexposure; supervised the California cholinesterase monitoring program; participated in refining the California cholinesterase monitoring rules; and authored numerous articles on the effects of pesticides, including articles dealing with cholinesterase inhibition and cholinesterase testing.</p> <p>Dr. O'Malley testified that monitoring of blood cholinesterase levels is the most effective and economical known method for tracking exposures to potentially dangerous levels of OPs and CBs in the work place.</p> <p>Cholinesterase monitoring has been used worldwide; thus, a large amount of information is available on its use as a tool to prevent poisoning.</p> <p>Cholinesterase samples have many of the features of an ideal biomarker of exposure and effect; and they offer a combination of specificity, simplicity, and rapidity; automation; relative noninvasiveness; and relatively low expense. Cholinesterase monitoring for workers who regularly handle highly toxic OPs and CBs is comparable in utility and effectiveness to the most</p>	<p>The department's feasibility determination, which is based on the use of a single laboratory using a consistent method to provide both baseline and periodic cholinesterase tests, is discussed in more detail in the main body of the CES. The method for conducting the cholinesterase testing, as set forth in the final rule, appropriately addresses the need for a standardized method.</p>

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	<p>appropriate of the mandatory medical monitoring standards that have been adopted under the Occupational Safety and Health Act (“OSH Act”) and WISHA.</p> <p>Dr. Matthew Keifer also testified in the <i>Rios</i> litigation. He was the principal scientist advising L&amp;I’s Technical Advisory Group on cholinesterase monitoring. He has been an assistant professor in the University of Washington Departments of Medicine and Environmental Health. He has diagnosed and treated farm workers for pesticide poisoning, done research on pesticide poisoning, its effects, and cholinesterase monitoring; and published a number of articles on the effects of pesticides, including articles on cholinesterase testing. When asked why cholinesterase testing was commonly used, Dr. Keifer testified:</p> <p>[Cholinesterase] has the advantage of being readily accessible from a sampling point of view in that it can be done in a simple blood test. It’s generally available in many laboratories. Commercial laboratories can usually do it. It’s a relatively straightforward test. It is – cholinesterase as an enzyme is the direct target of the toxicologic effects of organophosphate and carbamate pesticides, and it’s presumably a reflection of toxicologic impact of pesticide exposure . . .</p> <p>It’s also – cholinesterase is probably the best studied enzyme in the world, and it’s one of the earliest enzymes about which or for which its structure has been clearly identified.</p> <p>Dr. Keifer also testified that cholinesterase monitoring is far cheaper than other testing for pesticide exposure.</p> <p>Dr. O’Malley and Dr. Keifer both note that cholinesterase monitoring has some technical constraints. For example, because different cholinesterase testing methods may produce differing results, there is a need for standardization of methods or a conversion factor to standardize results.</p>	
5.10	L&I Should Consider the Following Evidence from the California Studies and its Relevance for Washington	The department has concluded, based on a review of the entire record, that a significant risk exists, thereby requiring regulation under WISHA. This is

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	<p>In 1985, scientists from the California Department of Health Services undertook an extensive review of that State's cholinesterase monitoring program. The review included a survey of 542 agricultural pesticide handlers whose cholinesterase levels were monitored under the program. The scientists' report concluded that "[m]edical supervision with cholinesterase monitoring is an important health protective measure for employees who regularly handle organophosphate or carbamate pesticides." The researchers further concluded that medical supervision with cholinesterase monitoring can:</p> <ol style="list-style-type: none"><li>1. Prevent further exposure of asymptomatic workers with depressed cholinesterase activity levels, thereby preventing pesticide poisoning;</li><li>2. Enable identification of workers who have been overexposed prior to reaching the removal threshold, and enable examination of their work safety practices;</li><li>3. Prevent chronic illness resulting from overexposure;</li><li>4. Increase worker consciousness of the toxicity of the chemicals used in the work place; and</li><li>5. Determine when it is safe for a worker to return to activities that may involve pesticide exposure after an illness occurs.</li></ol> <p>The 1985 review of the California program also found that 23% of the 542 workers examined had cholinesterase levels below 80% of their baseline (<i>i.e.</i>, normal) levels. This shows that a very significant percentage of pesticide handlers had substantial exposure to cholinesterase-inhibiting pesticides and a significant risk of poisoning.</p> <p>The most recent published survey of workers covered by the California program reported the results of 103 worker-years of cholinesterase monitoring which occurred in 1989 and 1990. This study by Fillmore and Lessenger found that 24% of the workers followed had to be removed from exposure because their cholinesterase depression exceeded the limits established under the program, and 5 percent of the workers had to be removed twice. This study indicates that workers who regularly handle OP and CB pesticides face a very significant risk of poisoning. Fillmore and</p>	discussed in more detail in the main body of the CES.

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	<p>Lessenger also found that the relative risk of toxic symptoms for workers whose cholinesterase levels were depressed to 60%-80% of their baseline early in the season (May or June) was over 9 times the risk for those workers whose monitoring levels were above 80% of their baselines during those months. This finding is very important because it shows a high risk of developing illness due to exposure that triggers a response under the cholinesterase monitoring program. After reviewing data on pesticide usage and incidents in Washington agriculture, Dr. Michael O'Malley testified that none of that data indicates that farm workers who regularly handle OP and CB pesticides face a significantly lower risk than workers performing similar tasks in California. Dr. O'Malley found, in fact, that the risk of OP and CB poisoning among agricultural pesticide handlers is <i>greater</i> in Washington than in California because California has reduced the risk to handlers by requiring "closed systems" for mixing and loading Category I (highest acute toxicity) pesticides. Closed systems limit spilling, splashing and inhalation exposure among pesticide handlers.</p> <p>Opponents of cholinesterase monitoring have asserted that OP and CB use has changed so much since the time of the California studies that monitoring is no longer needed. In our November 13, 2002 letter to Michael Silverstein we reviewed USDA pesticide use data for California near the time of the Fillmore &amp; Lessenger study (blood samples taken in 1989 and 1990) as compared to current pesticide use data for Washington State. Since data was not available for most California crops for years prior to 1993 and 1994, we used those years for comparison to the most recent years in Washington State for which data is available.</p> <p>Attachment K to the November 13<sup>th</sup> letter shows that, in a few cases, the percentages of acres on which specific pesticides were used are equivalent between the two states. In some instances larger percentages of acreage were treated with certain OP or CB pesticides in California in 1993 or 1994 than in Washington State in 2000 or 2001. In just as many other cases, however, the percentage of acres on which certain pesticides were applied in Washington in 2000 or 2001 greatly exceeded the California percentages in</p>	

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	<p>1993 and 1994. For example, 73% of Washington's apple acres in 2001 were treated with azinphos-methyl (AZM), while only 42% of California's were treated with AZM in 1993. The Washington rate per application in 2001 was .94 pounds per acre compared with California's rate in 1993 of 1 pound. In other words, Washington apple orchard workers applying AZM in 2001 applied about the same number of pounds per acre per application, under less effective worker protection regulations than those in place in California in 1989-90. It is revealing to review the Apples Chart column for Washington rate per application for 2001 and the neighboring column which contains California's rate per application in 1993. For the Category 1 and 2 OPs and CBs, the Washington rate per application is higher for 4 out of 6 pesticides. For AZM, California's rate exceeds Washington's very slightly but is in the same range. A review of the other charts shows that rates per application are similar, with many examples of Washington's rate per application exceeding California's.</p> <p>In several instances, Washington did use fewer applications per year in 2000 or 2001 than California did in 1993 or 1994. When fewer applications are made, workers will have fewer handling hours to count towards the thresholds for requiring monitoring. When workers do engage in applying or otherwise handling pesticides, they continue to face serious risks comparable to those faced by workers in California near the time of the Lessenger study.</p>	<p>We also attached to the November 13<sup>th</sup> letter a set of bar graphs which compare Washington use in the most recent year for which data is available with use ten years earlier. (Attachment L to the letter) As you can see from this material, in a few instances the percentage of acres treated with a given pesticide is lower than the percentage ten years ago, but it still remains very high. In many cases, however, use of specific OP and CB pesticides was actually higher in 2001 than ten years ago. The graphs illustrate these trends and also provide details on number of applications, rates per application, rates per crop year, and total volumes used. In general, current rates per</p>

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	<p>application are comparable to what they were ten years ago; and in many instances the amount applied per acre per application is greater than it was ten years ago.</p> <p>Even if Category 1 and 2 OPs and CBs were now in scant use, workers handling them for more than 30 hours or 6 days in a 30-day period would need monitoring protection. And growers who had ceased to use Category 1 and 2 OPs and CBs would not have to provide monitoring for workers. Unfortunately, however, the USDA pesticide use data reveals a very different reality. The use of Category 1 and 2 OPs and CBs remains very high, with increases over prior years for many of these pesticides.</p> <p>Opponents of mandatory medical monitoring also assert that Worker Protection Standards (WPS) adopted in Washington since the time of the Fillmore &amp; Lessenger study greatly reduce the risks that workers face. They fail to note, however, that California had pesticide regulations in place when data was collected for the Fillmore &amp; Lessenger study that were <i>more effective</i> than Washington's current WPS. Contrary to the assertion that personal protective equipment (PPE) was not required for pesticide handlers before the WPS were adopted, the 1988 California regulations included requirements for eye protection (§ 6738(b)), gloves (§ 6738(c)), chemical resistant protective clothing (§ 6738(d)), and respiratory protection (§ 6738(e)).</p> <p>As Dr. O'Malley noted, California also had the requirement for closed systems for mixing and loading Category 1 pesticides. Finally, California had the requirement for investigations of workplace practices when cholinesterase levels are detected at 80% of the baseline or below. This requirement should reduce the number of workers who have to be removed from exposure.</p> <p>Dr. O'Malley further testified in <i>Rios</i> that:</p> <p>The Worker Protection Standards are not a “magic bullet” that have eliminated the need for additional protection. California had pesticide regulations that were, on the whole, more protective of pesticide handlers</p>	

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	<p>than the Worker Protection Standards during the period when the Ames study and the Fillmore and Lessenger study showed high rates of overexposure among handlers covered by the California monitoring program. As the Ames study found, cholinesterase monitoring is necessary to determine whether the required work safety practices are being effectively implemented to protect pesticide handlers. Thus, the California studies provide compelling evidence of the risk to Washington agricultural pesticide handlers from cholinesterase-inhibiting pesticides. Cholinesterase monitoring continues to be necessary and appropriate to protect worker health.</p>	<p>The department has made its determinations based on the entire record in the present rulemaking, rather than relying upon the recommendations and findings of the TAG report.</p>
5.11	<p>L&amp;I Should Consider the Following Findings and Conclusions of L&amp;I's Technical Advisory Group.</p> <p>As the Supreme Court noted in <i>Rios</i>, L&amp;I's Technical Advisory Group (TAG) reviewed "the most current research" available in 1995. Based on that research, the TAG made the following findings and conclusions:</p> <ol style="list-style-type: none"> <li>1. "The National Institute of Occupational Safety and Health (NIOSH) and the World Health Organization (WHO) recognize routine blood cholinesterase monitoring as an important tool in the prevention of poisoning among workers who regularly handle these [OP and CB] pesticides."</li> <li>2. "Cholinesterase monitoring offers an opportunity for medical monitoring that responds to individual workers or individual worksite problems and for surveillance activities that serve to protect all workers at risk."</li> <li>3. "'[The cholinesterase] surveillance system in California has succeeded in reducing the number of work-related pesticide illnesses.'</li> <li>4. "The Technical Advisory Group recommends cholinesterase monitoring for all occupations handling Class I or II organophosphate or carbamate pesticides."</li> </ol>	<p>Although identifying situations where required PPE is not effective is one benefit of medical monitoring, the department has concluded that the more important</p>
5.12	<p>Cholinesterase Monitoring Is Needed to Determine Compliance with, and Effectiveness of, PPE and other Worker Protection Standard Requirements.</p>	

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	<p>Because of the high toxicity of cholinesterase-inhibiting pesticides, PPE and other protections required by the WPS do not provide adequate protection even when there is ideal compliance with the WPS. EPA's Registration Notice on Worker Risk Mitigation for Organophosphate Pesticides states:</p> <p>EPA is particularly concerned for workers and handlers because of the relatively high risks indicated by current assessments, the acute toxicity of these compounds coupled with the large volume of chemicals handled, and the potential for accidental exposure to concentrated products frequently used in commercial applications. . . . The occupational risk assessments completed thus far for the OPs have shown that, <i>with only a few exceptions, worker and handler [Margins of Exposure (MOEs)] for these pesticides exceed the Agency's level of concern</i> (i.e., have MOEs &lt; 100). In a number of cases, even with maximum personal protective equipment (PPE), such as double-layer clothing, chemical resistant gloves, and appropriate respirator, or with engineering controls, such as closed mixing/loading systems and enclosed cabs/cockpits, calculated MOEs are still lower than 100 [exceeding the EPA's level of concern]. Emphasis added.</p> <p>Thus, even with ideal compliance and the additional engineering controls that farm workers have requested <i>and not received</i>, such as closed systems for mixing and loading and enclosed cabs for spraying, the exposures from OPs exceed the EPA's level of concern.</p> <p>Our client, Arnoldo Navarro, became sick from applying pesticides in January 2001, even when he was wearing full PPE. He suffered nausea, headache, nosebleed, and irritation of his eyes and throat.</p> <p>A study of 25 workers who mixed and sprayed the OP pesticide malathion demonstrated the limitations of PPE. Through the use of fluorescent tracers in the pesticides, the researchers determined that all workers had measurable hand exposure despite the use of neoprene gloves. All workers were also exposed on their face and neck, areas that were not protected by PPE.</p> <p>Workers who wore coveralls had the heaviest deposition of pesticide exposure near the openings of their garments (collars and sleeves). And 24</p>	<p>benefit is identifying situations where the required PPE is not being used (or is not being used properly). However, the final BCD provides discussion of the potential for PPE requirements themselves to be inadequate.</p>

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	<p>of the 25 workers received exposure to the arms or torso, regions covered by protective clothing. Cholinesterase monitoring is needed to determine when the required PPE is not protecting the worker.</p> <p>Cholinesterase monitoring is also needed to determine when noncompliance with the WPS is resulting in overexposure. A recent report by Washington Department of Agriculture (WSDA) documented widespread noncompliance by agricultural employers with the worker protection standard. See WSDA Report, "Worker Protection Standard: Problems and Issues Identified During WSDA Inspections FY 2002," by Ofelio Borges of WSDA's Pesticide Management Division. Of 37 agricultural workplaces inspected, "only 24% were complying with all WPS regulations." 61 WPS violations were found in just 37 inspections, including 4 violations of personal protective equipment (PPE) requirements, 17 violations of training requirements, 25 violations of decontamination supply requirements, and a number of violations of central notification requirements.</p> <p>Noncompliance with the WPS requirements has had a direct effect on our clients. When Saul Carmona's employer failed to provide filters for his mask, he passed out after spraying Guthion. At another orchard, Mr. Carmona received old, worn out PPE that his employer refused to replace. Mr. Carmona suffered nausea and vomiting from mixing Guthion with the old equipment.</p> <p>Our client, Ambrosio Marin, received very little training about pesticides before applying them; the filter in his respirator was not changed for over a month; he was supplied with glasses that did not meet eye protection requirements; and the company didn't provide water for emergency washing. On two occasions while mixing chemicals, including Guthion, the pesticide mixture splashed into his eyes, and he has consequently suffered from persistent burning and itching eyes and blurred vision.</p> <p>Cholinesterase monitoring is needed to help workers determine where there are problems with their equipment and to obtain better information about their exposure so that they can protect themselves. Without cholinesterase</p>	

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5.13	monitoring, workers have been afraid to complain about their exposure for fear of losing their employment.  Cholinesterase Monitoring is Needed to Maintain Worker Health and Productivity.	One of the primary benefits of the rule is the prevention of illness and the resulting effects, as well as the early identification and treatment of illness when it does occur.  As the Ames study reported, a basic purpose of cholinesterase monitoring is to prevent further exposure of asymptomatic workers with depressed cholinesterase activity levels, thereby preventing pesticide poisoning. The acute and long-term symptoms are well-documented in the draft BCD and under heading B.1. above.  Since suffering pesticide poisoning, our client, Juan Rios, has felt exhausted and experienced sneezing, a running nose, and irritated eyes and throat when he applied pesticides. These symptoms lasted approximately 60 days out of a four-month spraying season when he was a pesticide applicator. Now that he is a supervisor and doesn't perform spraying, he still feels symptoms for an average of 30 days during the spraying season. These symptoms include difficulty breathing, coughing, sneezing, runny nose and irritation of the eyes, throat and nose.  Arnoldo Navarro continued working after both of his pesticide exposure incidents because he had to support his family. During the majority of the time that he worked spraying pesticides following his exposure, he experienced nausea and irritation in his throat, eyes and nose. His illness prevented him from working at his normal speed. He still suffers from severe headaches and difficulty breathing.  Saul Carmona continued working following his exposure incident, despite vomiting, bad stomachaches, dizziness, weakness, excessive perspiration, and occasional blackouts. He couldn't afford to go to the doctor, and never complained. He finally left the job after the spray season was over -- despite the need to provide for his family -- because he felt extremely sick. Later Mr. Carmona obtained another job that involved spraying, and suffered another pesticide illness. Following that illness, he experienced difficulty breathing, chills, dizziness, a dry mouth, and eye irritation while working

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	during spray season.  Following Ambrosio Marin's poisoning incident, his doctor advised Mr. Marin that he had an allergy to chemicals and that he should stay away from them. Mr. Marin has no alternative to working in the fields where pesticides are used.  Cholinesterase monitoring is needed to prevent both acute and chronic illness from cholinesterase-inhibiting pesticides.	One of the primary benefits of the rule is the prevention of illness and the resulting effects, as well as the early identification and treatment of illness when it does occur.
5.14	Cholinesterase Monitoring is Needed to Prevent Adverse Economic and Social Impacts on Handlers and Their Families.  Prevention of pesticide poisoning through cholinesterase monitoring will prevent the kinds of adverse effects that our clients and their families have suffered. After being exposed to pesticides at work, Juan Rios has often been too exhausted to do chores around his house or play with his kids. Similarly, Arnoldo Navarro cannot do his share of the family chores because of fatigue due to his pesticide exposure. Mr. Navarro is also afraid of making his wife and children sick from the pesticides that he brings home on his clothes and on himself.  As detailed under heading B.1 above, acute poisoning from OP pesticides can result in long-term impairments in vigilance, concentration, information processing, psychomotor speed, memory and language, as well as long-term anxiety, irritability and depression. These impairments have a serious adverse impact on the ability of farm workers to provide financial and social support for their families. Prevention of these long-term effects is a significant benefit of cholinesterase monitoring.	One of the primary benefits of the rule is the early identification and treatment of illness when it occurs. The BCD also acknowledges the value of ensuring that claims that are occurring be appropriately identified.
5.15	Cholinesterase Monitoring is Needed to Identify Existing, but Undiagnosed, Workers' Compensation Claims and Provide Access to Health Care.  Cholinesterase monitoring will provide agricultural pesticide handlers with	One of the primary benefits of the rule is the early identification and treatment of illness when it occurs. The BCD also acknowledges the value of ensuring that claims that are occurring be appropriately identified.

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5.16 L&I Should Consider the Benefits of Workplace Investigations.	<p>objective evidence of pesticide poisoning, and help them obtain the medical care and time loss compensation to which they are entitled.</p> <p>The draft BCD considers the benefits of worker removal from cholinesterase monitoring, but fails to consider benefits from workplace safety investigations that will occur when blood cholinesterase is reduced more than 20% from the baseline. The Ames study of 542 workers found that identification of workers who have been overexposed prior to reaching the removal threshold and enabling examination of their work safety practices is one of the primary benefits of cholinesterase monitoring. The Ames study found that 23% of the 542 workers examined had cholinesterase levels that were depressed more than 20% from their baseline after handling pesticides. The safety investigation requirement will therefore benefit a high percentage of workers. It will also benefit workers who do not (or do not yet) have significantly reduced cholinesterase levels and who are affected by the same workplace practices that can be identified and corrected as the result of the safety investigation.</p>	<p>This was mentioned in the draft BCD, but it is discussed in more detail in the final BCD.</p>
5.17 Probable Costs of the Rule	<p>We join in the comments by Earthjustice on L&amp;I's assessment of the probable costs of the rule. We would like to emphasize that the draft BCD unnecessarily overstates employer costs when employers shift pesticide application practices by discontinuing or reducing covered pesticides and/or keeping workers' hours below threshold for coverage of the rule. L&amp;I states that it treats the cost of the shift in practices as identical to the cost of complying without any change in work assignments. The agency acknowledges that this "clearly overstates employer costs" because employers would be unlikely to change practices unless they saved money by doing so. L&amp;I asserts that this approach is most appropriate because it assumes there is no data available to estimate the cost of alternatives. In fact, recent studies have found that growers can use alternatives to</p>	<p>The conservative approach to analyzing the costs of the rule reflected by treating the cost of substituting other practices for those covered by the rule does, as was acknowledged in both the SBEIS and the draft BCD, overstate the costs of compliance. However, the department considers it the most appropriate method based on the information currently available in the record. While one commenter says that the department cannot "ignore" the survey data, the survey data does not provide sufficient information to calculate a cost of these shifts in practices; the data provided elsewhere in the record confirms that alternatives are available, but that does not provide sufficient information to calculate the cost of these shifts in practice. By acknowledging that the costs are overstated somewhat (and to an unknown degree), L&amp;I is indeed relying upon the best available data. In addition, using an assigned value equal to the value of complying without a change in</p>

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	<p>cholinesterase-inhibiting pesticides with little difference in cost. First-year (2002) results in a three-year study of 21 orchards (15 apple and 6 pear) by the Washington State Tree Fruit Research and Extension Center found little difference in cost or effectiveness between using and not using broad spectrum OP pesticides. Each of the 21 orchards was split in two portions, with half of each orchard using no OP pesticides and the other half using OP pesticides such as Guthion and Lorsban as a supplement to mating disruption for control for codling moth, leafrollers, <i>Iaconobia</i> fruit worm, and other pests.</p> <p>An earlier study of an apple orchard under high codling moth pressure at Orono, Washington found that the use of pheromone mating disruption cost less than multiple applications of OP cover sprays. The Washington State University Cooperative Extension researcher explained that mating disruption “is not only cost-effective for many tree fruit growers, but provides many benefits compared with traditional broad spectrum insecticides, such as reduced spray applications, reduced worker exposure, compatibility with biological control, and economical gains in some cases.”</p>	<p>pesticide application practices is an appropriate method of evaluating the cost of a decision that the employer would not have made without the impetus created by the rule.</p> <p>Contrary to the comments, the department has concluded that it is not a violation of WISHA (which does not itself require a benefit-cost determination) to use such a conservative approach in developing the BCD. Nor does the APA, RCW 34.05.328(1)(c), prohibit the methodology used by L &amp; I in preparing the BCD. Rather, the methodology used by L&amp;I in the BCD is based upon practices and approaches used in the economic community when conducting such analyses.</p> <p>It would flout the plain purpose of WISHA to say that the department, which has already determined based on the information available (and its conservative assumptions) that the probable benefits outweigh the probable costs, must wait to adopt the resulting rule until it can do additional economic analysis and obtain additional information allowing it to modestly reduce the cost estimate. In the resulting delay created by a search for a more precise BCD, workers would go unprotected.</p> <p>Contrary to the comments, the department has not failed to use the survey responses indicating there will be a change in practice. Indeed, those results and the likelihood that they will reduce the costs are explicitly acknowledged by the SBEIS, the draft BCD (as quoted in the comments) and the final BCD. The commenters err, however, in their belief that the department must arbitrarily assign a lower value in the face of the unknown change in costs. The most appropriate approach is the conservative approach that recognizes that those shifts in applications practices will cost no more than would complying with the rule without such a shift. Because that is the maximum cost, and because it is not possible to readily estimate a more likely cost (beyond acknowledging that it will be below the maximum), that is the cost reflected by the quantitative portion of the analysis. Given the APA’s clear acknowledgement of the consideration of qualitative costs and benefits, the commenters’ insistence on the exact</p>

L&I’s Rationale For Ignoring The Survey Results Is Contrary To WISHA’s

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	<p>Requirement That L&amp;I Use The Best Available Evidence When Creating The Medical Monitoring Rule</p> <p>L&amp;I's rationale for not using the growers' responses is contrary to WISHA because the department is refusing to use the best available evidence when creating the rule. WISHA requires L&amp;I to use the "best available evidence" when creating a health and safety standard. RCW 49.17.050(4). The proposed medical monitoring rule is a health and safety standard under WISHA. CBD, at 3 n.4. L&amp;I conducted this survey for use in creating the CBD. L&amp;I's rationale is contrary to WISHA because it disregards an overwhelming answer to a question on the survey.</p>	<p>quantification in the absence of data on which to base such an estimate is itself irrational.</p>

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	CBD, at 14 (emphasis added). Costs that are, by L&I's own admission, “clearly overstate[d]” are not “probable.” Since L&I cannot ignore probable costs, the agency must integrate the survey responses into the agency’s CBD for the rule in order to comply with the APA.	The department agrees that better data is desirable (and the final BCD, like the draft BCD, explicitly states the availability of such data as a benefit of the rule). However, the department believes that sufficient information exists to make a determination based on the best available evidence that the probable benefits of the rule outweigh its probable costs. Indeed, the APA acknowledges that explicit quantitative data may not be available to an agency when preparing a BCD, by requiring agencies to use “qualitative” as well as “quantitative” data to complete this analysis. That determination is discussed in more detail in the BCD.
5.18	We disagree with the conclusion of this analysis, that the benefits exceed the costs in this proposed regulation. However, we agree with the unstated but equally obvious conclusion: the department currently lacks the data to adequately assess the benefits and costs. Farm Bureau is committed to working with the Department to collect the data that will be necessary for the Department to make an accurate assessment of this regulation.  The Department apparently made no attempt to perform even a rudimentary cost-benefit analysis. For example, the department states that a number of pesticide poisonings would be prevented by the rule. How would that be?  There is no connection between acute exposure and a rule that measures low-level exposure. Surely, L&I can venture a guess as to how many pesticide poisonings we have now, and how many less we believe that we will have as a result of the regulation?	The BCD does not claim that acute poisonings would be prevented to any significant degree (although it is likely that some acute poisonings that currently go undiagnosed would be identified), and that some other acute poisonings would be prevented due to enhanced use of PPE – based on the estimated removal rates, both the draft BCD and the final BCD provide numbers of poisonings that would be identified in the early stages before symptoms became severe. As discussed in both the draft BCD and the final BCD, the data is not available to enable quantitative estimates of the illnesses that will be prevented by changes in employer practices or by early identification of depressions triggering the work practice investigation requirement to be made with any reliability, and in the absence of such information, the department does not consider it appropriate to “venture a guess.”
5.19	<u>Prevention of Serious Illness After Over Exposure</u>  There is no data for the central estimate of 3 percent worker removals. The only data available, from California, indicates worker removals in the one percent range.  The department assumes 3 percent of workers, or 37 workers in the first year, will be removed. The cost benefit analysis makes no mention of the probability that these removals will be for a false positive result or some	As discussed in the SBEIS, the draft BCD, and the final BCD, the 3 percent removal figure is based on California data indicating a 4.8 percent removal range, with adjustments based on the department’s analysis of the various factors likely to affect that rate. Applying a one percent figure based on Dr. Das’ preliminary analysis of the California system that has been in place nearly three decades would disregard the effect that cholinesterase monitoring itself is likely to have on the number of depressions. This assessment is shared by Dr. Das herself.

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	<p>other problem in the testing protocol. Cholinesterase testing is not well suited for the degree of accuracy that is required. The California data suggests that ten percent of the tests will be abnormal, but the vast majority of these will be attributed to something other than workplace exposure to pesticides.</p> <p>The department received testimony that worker removal would be anywhere from less than one percent up to 25 percent. This is more evidence that we have no idea what the benefit of testing would be.</p>	<p>As discussed in the specific response to comments from the Washington Farm Bureau, the department does not believe there will be any discernible number of “false positives” and the commenter’s conclusion to the contrary is based on a misunderstanding and misapplication of the existing data.</p> <p>The 24 percent estimate is discussed in previous responses and is not likely to reflect the average Washington employer covered by the rule; the “less than one percent” comments came from the same individual making the comment about the uncertainty of the data, and is discussed in more detail in the specific response to comments from the Washington Farm Bureau. If, however, the department <i>did</i> have data that indicated no more than that the number of handlers poisoned by covered pesticides ranged somewhere between less than one percent and 25 percent, that would represent a significant risk of poisoning and would itself provide a sufficient basis for rulemaking.</p>
	<p>On page 5 and 6 of the analysis, the Department mixes data regarding <b>acute</b> poisonings interchangeably with new data regarding low level exposure. From there, the analysis recounts anecdotal evidence from focus groups and other information to suggest that the central estimate of 3 percent may be reasonable.</p>	<p>The department has <i>not</i> mixed data regarding acute and long-term exposures (in spite of earlier suggestions in the record that it was “amazing” that the department did not estimate the number of handlers poisoned by long-term exposures based on claims data about acute exposures). The department <i>does</i> consider the claims regarding acute exposures as an indicator that problems with work practices and appropriate use of PPE and engineering controls continue to exist, and the department recognizes that such problems are likely to result in other poisonings not reported to the workers compensation system precisely because they are <i>not</i> acute, or because the cause was not recognized even though it <i>was</i> acute.</p> <p>The focus groups and other studies confirm a wide body of evidence that pesticide-related illnesses, and occupational illnesses in general, are under-reported. But the three percent central estimate is based on modifications to the 4.8 percent estimate found in the only completed study of the California removal rate (and the only one early enough in the cholinesterase monitoring process to be less affected by the changes in poisoning levels resulting from the cholinesterase</p>

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		<p>monitoring rule itself). The number may be somewhat higher, and it may be somewhat lower – which is why the SBEIS, the draft BCD, and the final BCD all include a high-middle-low range from between 1.2 percent and 4.8 percent.</p> <p>The rule provides a mechanism for data collection and rule evaluation.</p>
5.20	<u>Greater Certainty About Frequency of Pesticide Over Exposure</u>	<p>Farm Bureau strongly agrees with the statements in this section. It is vitally important that we accurately assess costs and benefits of this regulation in the next two years.</p>
5.21	<u>Probable Costs of the Regulation</u>	<p>The costs appear to be as represented in the survey accompanying the small business economic impact statement, with a few changes to reflect our comments. It is interesting to note that the Department spends much time speculating that farm worker pesticide exposure is underreported, but makes no estimate of the amount of underreporting of pesticide use by farmers. In other words, the Department blithely assumes that a telephone survey person can call up a farmer, state that he or she is a government contractor, and assume that the information will be accurate. We look forward, as the Department does, to the opportunity to collect more realistic information.</p> <p>The department did not include many costs in this cost benefit analysis. For example, there is no cost associated with the workplace investigation that is necessary when there is a lowered cholinesterase level. There is no cost associated with the many instances where the tests reveal a problem, when none exists. There is no cost associated with the Department's increased cost to monitor compliance with the regulation. Since most of the benefits that the Department recognizes are qualitative, the Department has failed to mention the qualitative cost to workers who will be subjected to this intrusive testing.</p> <p>As discussed in more detail in the specific response to comments from the Washington Farm Bureau, the department does not expect a meaningful number of false positives.</p> <p>The department does not anticipate an increase in costs to monitor compliance with the rule – the department already inspects agricultural workplaces and has sufficient enforcement discretion to focus resources on this issue as necessary.</p> <p>Making a test available to workers that can protect their health, and to which they are not required to submit, cannot accurately be described as a cost to those</p>

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5.22	<p>The Washington Department of Labor and Industry (L&amp;I) has analyzed the costs and benefits of implementation of <b>WAC 296-307-148 “Cholinesterase Monitoring”</b>. The costs of implementing the rule were estimated quantitatively and presented as a range that spans a low of \$723,887 in the first year of the rule to a high of \$2,552,811 during the second year of the rule. The central tendency estimate ranged from \$894,772 during the first year to \$1,886,950 during the second year.</p> <p>In contrast to the precise projection of costs, L&amp;I provided a qualitative narrative of benefits, and defended its perspective by citing scientific documents that putatively agree with its narrative. It furthermore added “weight” to its benefits analysis by analogizing the Rios decision to a U.S. Supreme Court decision (ATMI vs. Donovan) supporting the primacy of worker health above all other considerations save those making attainment of this “benefit” unachievable.</p>	<p>The BCD’s reference to the Karr study is one reference among several suggesting the presence of some level of poisoning from pesticides. The department agrees with several of the criticisms of the study; if it did not, the department would have estimated the medical removal rate at 10 percent, rather than 3 percent. The 3 percent figure itself is reduced from the 4.8 percent figure in the research on which it is based in part because of the acknowledged decrease in the toxicity of certain pesticides (as well as other factors). Interestingly, the 2.2 percent figure referenced in the commenter’s review of the Karr study falls between the 1.2 percent lower value and the 3 percent central value, although the department believes a more careful analysis of the Karr study suggests a figure of roughly 8 percent.</p> <p>Contrary to the suggestion here, the department has recognized the value of changes in delivery methods. Both the proposed and final rule recognize the reduced risk of poisoning when closed systems (including water-soluble packaging) are used by excluding the hours mixing and loading such systems from handling hours in relation to periodic testing.</p> <p>The department does not, however, assign much importance to the change in PPE requirements precisely because medical monitoring appropriately works in tandem with other requirements by identifying breakdowns in appropriate PPE use or work practices (the same argument can be made – and was made in the record – in relation to the use of closed systems, but the department determined that the value of creating an incentive for the use of such systems justified an exception in that limited circumstance).</p> <p>L&amp;I stated that it has balanced the benefits against the costs of the rule. In short, L&amp;I essentially has invoked elements of the precautionary principle as its basis for benefits. L&amp;I’s interpretation of both the U.S. Supreme Court Ruling in the ATMI vs. Donovan case and the WA State Supreme Court ruling in the Rios case has overlooked the important element of cost effectiveness. In essence, the WA State Supreme Court invoked the concept of cost effectiveness to indicate that a policy could over regulate by mandating more than necessary to achieve the desired result. L&amp;I presumably considers that the published scientific literature based on California ChE monitoring experiences as indicative that monitoring was responsible for protecting workers and is thus applicable to the current state of pesticide use and practices in Washington State. Furthermore, L&amp;I has invoked the “unpublished” study of Karr et al. (1995) as indicating that “10% of agricultural workers had ChE depression levels at the end of the application season consistent with proposed trigger levels”. Again, the</p> <p>A more detailed discussion of the studies referenced here and the department’s use of the relevant research information is provided in the specific response to comments by the Washington Farm Bureau.</p>

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	L&I's leap of logic to "prove" benefits presumes that ChE monitoring will somehow reduce this 10% proportion toward a theoretical zero "overexposure".	<p>Unfortunately, L&amp;I's interpretation of the California experience as published and the Karr et al. report that they seem to heavily rely on is uncritical and specious if used to describe benefits in Washington State Agriculture as it is practiced today. For example, L&amp;I failed to understand that the use of OP insecticides has dramatically changed, both in specific chemicals and in amounts. All OP insecticides are not the same in terms of potential hazards. Differences in hazard are easily proved by both an examination of the differences in dermal toxicities for compounds prevalent in California agriculture during the 1980's and what is being used in this current decade. A comparison of dermal toxicities for older, no longer used OPs indicate an association of the majority of reported pesticide illness with pesticides having dermal LD50 values less than ~50 mg/kg (namely, ethyl parathion, methyl parathion, and mevinphos). Ethyl parathion and mevinphos have not been registered for use for nearly a decade. Methyl parathion has not been registered for use in fruits for at least two years now.</p> <p>In contrast to the dermal toxicities of OP insecticides used during the 1980's, currently used OP insecticides have much higher LD50 values that are significantly greater than 200 mg/kg and therefore much less likely to cause illness or even cause detectable ChE depression of levels greater than 20% given their very low efficiencies of dermal penetration. The two exceptions are methamidophos (dermal LD50~118 mg/kg) and azinphosmethyl (dermal LD50~155 mg/kg). However, the use of both compounds has dropped precipitously since the 1997 lawsuit of Rios.</p> <p>To maintain that benefits are qualitatively high without consideration of pesticide hazard seems faulty logic in light of the importance in change of OP insecticide use. Not only do the dermal LD50's give evidence that there has been a big change, but examination of specific OP insecticides during</p>

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	<p>the 1980's in California that were responsible for the most cases of reported illness and thus overexposure also belies a conclusion that there would be a benefit to cholinesterase monitoring. L&amp;I should examine the publication by Brown et al. (1989). These researchers showed that the greatest proportion of reported illnesses were due to ethyl parathion and mevinphos alone. Of 238 reported illnesses resulting from OP overexposure during the time period 1982-1985, these pesticides were responsible for 44 and 49, respectively. Furthermore, a significant number of these cases could be attributed to either accidents or safety violations. With regard to currently registered OP insecticides, diazinon, dimethoate, and azinphos-methyl accounted for only 16, 16, and 12 cases of illness. All other OP-associated cases numbered less than 10. Interestingly, the most heavily used OP was chlorpyrifos, yet its use was associated with only 6 cases. As with the non-registered OPs, a substantial number of cases associated with currently registered OPs were the result of accidents and safety violations.</p> <p>In the light of no registration for use of mevinphos and the parathions, L&amp;I might presume a greater reliance on the other OPs. However, they would be wrong as evidenced by the trend in reduction of all OP insecticides and current use statistics. For example, in pome fruit production, which is the crop category with greatest OP use, azinphos-methyl use decreased over the last decade by over 40% despite the loss of ethyl and methyl parathion. Diazinon use on apples has approached nil. Chlorpyrifos use on pome fruits has been restricted to a dormant spray that would occur at a cooler time of year when handlers are most likely to face less discomfort with required PPE (personnel protection equipment).</p> <p>In addition to the changes in specific OP use and availability, requirements for PPE have been updated since implementation of the 1994 worker protection standard, as well as since registration review under the aegis of the 1996 FQPA. Thus, workers today are using greater PPE than during the 1980's. Moreover, the formulations of the most used OP, azinphos-methyl,</p>	

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	has changed to soluble packaging in defined units so handlers would not have to weigh out wettable powder material that is difficult to control.	In addition to the reliance on the outdated California studies as support for putative benefits, L&I has cited the unpublished Karr et al. study. L&I's has overlooked the peer reviewed publication by Karr et al. (1998) that seems to be essentially the same set of data to which they are referring. A critical analysis of this paper reveals the fallacious conclusion of 10% of workers with ChE depression above the threshold. Rather, the appropriate conclusion is that at most only 2.2% of workers experienced ChE depression exceeding proposed thresholds for action, and essentially only one worker accounts for that proportion. More importantly, the authors claimed problems in using the particular cholinesterase test that they relied on. Thus, there is no valid evidence to support the 10% figure that L&I used to support its contention of substantial benefits.  L&I argued benefits will accrue due to the prevention of pesticide illness. They cite the paper of Savage et al. (1988) on chronic neurological sequelae of acute OP poisoning and also other researchers on OPIDN (organophosphate-induced delayed neuropathy). The possibility of neurological sequelae does not prove that implementation of cholinesterase monitoring prevents such phenomena. Furthermore, they do not cite other work suggesting that chronic neurological sequelae do <b>not</b> arise from moderate exposure levels (Ames et al. 1995). For those cases that have shown high exposures and subsequent clinical poisonings give evidence to support the development of neurological sequelae, L&I has failed to understand what pesticides were used at the time of the studies and what the level of PPE was or the circumstances of exposure. Because the studies that L&I cites are from a database developed during the 1980's when the overwhelming majority of OP-related illnesses resulted in association with two no-longer registered pesticides (i.e., ethyl parathion and mevinphos), it is unreasonable to claim benefits for a situation that no longer exists.

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	L&I wrongly cites the avoidance of OPDIN as another benefit. All of the currently registered OP insecticides have been tested for the potential of OPDIN, and none have been found to cause this condition in the EPA-mandated test for this syndrome. Thus, avoidance of a disease that cannot be caused by the currently registered pesticides cannot be invoked as a benefit.	L&I has not considered studies that suggest cholinesterase monitoring may fail to provide protection by either being irrelevant to an exposure or being uncorrelated with illness. For example, the United Nations FAO sponsored a study to compare ChE depression in sprayers and non-handlers working in desert locust control in the arid environment of Mauritania (Aston et al. 2000). Monitoring did not show any difference in ChE levels between sprayers and workers who did not handle insecticides. These results were based on comparison monitoring of at least two pre-spray baselines with post-spraying ChE levels. The pesticides used included chlorpyrifos and diazinon. A study in Israel involving sprayers, orchard workers, and field hands showed minimal plasma and RBC ChE depression (<10%) when pre-season baselines were compared to in-season measurements (Richter et al. 1986). Serum acetylcholinesterase levels were not significantly correlated with either neurobehavioral performance or neurological abnormalities in studies of pesticide applicators in Egypt (Farahat et al. 2003). In short, evidence contrary to what L&I relied on for a benefits analysis suggests that very little benefit will accrue to ChE monitoring.  L&I stated that there is a significant risk of pesticide poisoning. Yet, the agency cites no risk assessment to support this blanket statement. In the context of regulatory toxicology, risk has a specific meaning that refers to the magnitude of the relationship between exposure and a well-defined toxicological endpoint, such as cholinesterase depression. Curiously, L&I could have cited EPA's worker exposure and risk analysis for all of the covered pesticides, yet they have not done so. Thus far, EPA seems to be the only agency that has even conducted a risk assessment. These worker

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	<p>risk assessments are conducted under the assumption of low use of PPE and maximum use of PPE including engineering controls. All the analyses are published as a publicly accessible report called the Registration Eligibility Decision Document. In determining that pesticide-poisoning risks are “significant” and therefore a de facto argument for benefits of ChE monitoring, L&amp;I failed to use the available EPA-generated information. If the agency had used EPA’s analysis of currently registered OPs, it would have noted that proper use of PPE reduces exposure to levels below EPA’s levels of concern as represented by a margin of exposure greater than 100. Because MOEs greater than 100 reflect cholinesterase depression as the toxicological endpoint and an uncertainty factor of 100 that is applied to the NOAEL (no observable adverse effect level) for ChE depression, EPA’s bona fide risk analysis suggest that there will be little likelihood of detecting any significant ChE depression if appropriate PPE are used.</p> <p>Finally, EPA’s worker risk assessment conclusions suggest a major fault behind L&amp;I’s cost-benefit analysis. The agency failed to discuss the benefits of just ramping up PPE requirements, on-site inspections for PPE, and increased in-field pesticide applicator training. Ironically, L&amp;I’s threshold of 20% ChE depression triggers a review of practices that could have lead to overexposure. But those faulty practices are already well known. In short, they are lack of appropriate PPE or improper use of PPE. Thus, the greatest benefit to worker safety and health will not come from an intermediate step of ChE monitoring. Rather, benefit will only come from appropriate and properly used PPE and/or other mixing and application practices as necessary. If L&amp;I wishes benefits to exceed costs, the only course of action is to implement a rule that focuses solely on PPE and worker practices.</p>	The data extrapolation suggested here assumes that the department knows the relationship between the survey data and exactly which pesticides are used. It
5.23	L&I Disregarded Cost Savings Related To The Required And Anticipated Use Of Closed Systems	L&I must incorporate the saving related to the required and anticipated use

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	<p>of closed systems into the CBD. The CBD states, “Hours spent mixing and loading using closed systems (as described in WAC 296-307-13045(4)(d)) will not be counted as exposure hours for the purposes of this rule.” CBD, at 4. L&amp;I applied this exemption, against the urging of Earthjustice and other commenters, to create an incentive for the use of closed systems. CBD, at 10. L&amp;I acknowledged that this incentive may “reduce or eliminate” the need to conduct periodic testing, which would reduce costs. CBD, at 14. However, the department ignores these cost reductions by stating, “L&amp;I does not have reliable data on the degree to which either situation occurs, and even less ability to determine the degree to which it will occur when the rule is in place.” CBD, at 14.</p> <p>L&amp;I should reduce its cost estimates by referencing the number of growers who are required to use closed systems and who will increase their use of these systems following implementation of the rule. L&amp;I has ample data to demonstrate the current number of growers who are or will shortly be required to use of closed systems with covered pesticides. L&amp;I enforces requirements for closed systems in Washington State. RCW 49.17.280; WAC 296-307-110; 296-307-11015; 296-307-13045. EPA pesticide registration documents require that applicators use closed systems in order to legally apply certain covered pesticides. (A listing of EPA reregistration documents is available at, <a href="http://cfpub.epa.gov/oppre/regstatus.cfm?show=rereg">http://cfpub.epa.gov/oppre/regstatus.cfm?show=rereg</a>). Closed systems are required when applying covered pesticides on some of the largest crops grown in the Washington, including apples, cherries, and pears. <u>Compare, CAROL DANSEREAU, DOCUMENT OUTLINING CLOSED SYSTEM REQUIREMENTS FOR SOME COVERED PESTICIDES and WASH. AGRIC.</u> STATISTICS SERVICE, WASH. STATE DEPT OF AGRIC., 2002 WASHINGTON AGRICULTURAL STATISTICS (2002). L&amp;I should use this information to estimate the number of handlers that will use closed systems when applying covered pesticides.</p> <p>Since the use of closed systems when applying numerous covered pesticides on many of the state’s largest crops is required, or will be required in the</p>	<p>does not. With that recognition, and for the same reasons discussed in detail in relation to the savings created by other shifts in pesticide practices, the conservative approach reflected in the BCD is the most appropriate.</p>

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	next few years, a significant number of growers will be familiar with the use of such systems. Additionally, some covered pesticides come in closed systems that are extremely convenient to use, such as water-soluble packaging. L&I should use these factors to reduce costs by extrapolating the number of growers who will voluntarily employ closed systems when the rule is implemented. Concomitantly, L&I should also increase the benefits resulting from the use of closed systems following the rule's implementation.	The final BCD acknowledges the modest value of information outside the state in the context of Washington rulemaking and acknowledges that there will be some continuing benefit to the information made available beyond the first two years of the rule's existence.
5.24	<p><b>L&amp;I UNDERESTIMATED THE BENEFITS OF A MEDICAL MONITORING RULE</b></p> <p>A. L&amp;I Underestimated The Scope And Duration Of Benefits Provided By The Medical Monitoring Rule's Information</p> <p>L&amp;I underestimated the medical monitoring rule's duration and breadth of benefits. The CDB states, “[O]ne of the primary benefits of a mandatory medical monitoring program is likely to be greater knowledge and certainty about the extent and effect of exposures to organophosphate and N-methyl carbamate pesticides. This benefit will largely be realized during the first two years of the rule's existence.” CBD, at 25. This two-year limit excludes multiple, long-term, high-level benefits for state, national, and international occupational and public health efforts.</p> <p>L&amp;I should assess the medical monitoring rule's benefits as part of a broader effort to evaluate and reduce occupational and public health threats from environmental contaminants. The rule's benefits will contribute to a range of such efforts within Washington State, across the nation, and around the globe. The rule's data and methodology will provide a wealth of long-term benefits to a host of vitally needed occupational and public health efforts.</p>	<p>The primary purpose of medical monitoring in the regulatory context is the protection of the monitored workers. The general value of medical surveillance in a broader context, while a genuine benefit, is of lesser importance (particularly when employers are required to pay the costs).</p>
5.25	<p><b>The Medical Monitoring Rule Is Part Of A Dynamic Process Of Evaluating, Preventing, And Addressing Occupational And Public Health Illnesses</b></p> <p>The CBD mischaracterization of the duration and extent of the benefits appears to flow from a misunderstanding of the nature and development of occupational and public health monitoring systems. The International Labor</p>	<p>The primary purpose of medical monitoring in the regulatory context is the protection of the monitored workers. The general value of medical surveillance in a broader context, while a genuine benefit, is of lesser importance (particularly when employers are required to pay the costs).</p>

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	<p>Organization defines “occupational health surveillance” as “the ongoing systemic collection, analysis, interpretation and dissemination of data for the purpose of prevention. Surveillance is essential to the planning, implementation and evaluation of occupational health programs and control of work-related ill health and injustices and the protection and promotion of workers’ health.” Ana Osorio, <i>Surveillance Systems for Pesticide Intoxications</i>, 8 INT'L J. OCCUPATIONAL ENVTL. HEALTH 1 (2002) (emphasis added). Thus, surveillance systems are not static arrangements. Rather, surveillance systems are individual components of a dynamic process where each constituent builds on the other and contributes to future advances in the prevention and diagnosis of illnesses.</p>	
5.26	A Medical Monitoring Rule Will Benefit Other Efforts To Address Occupational Illnesses	<p>These benefits are acknowledged in the final BCD.</p> <p>A medical monitoring rule will benefit state, national, and international efforts to address work-related illnesses in high-risk occupations and traditionally underserved populations. Four additional benefits of a rule include the development of a mechanism to: 1) Notify former workers of past occupational exposures and obtain information from such workers to improve exposure data for studies; 2) Report exposures by job task, which can aid future epidemiological analysis; 3) Develop historical monitoring data that can benefit the diagnoses and addressing of occupational illnesses; and 4) Create a database of exposed workers, which can help in determining eligibility of people to participate in future studies. Developing, implementing and refining the medical monitoring rule can benefit efforts to prevent occupational illnesses and accidents that may be indirectly caused by acute and chronic exposure to covered pesticides. A medical monitoring rule can also augment other on-going and planned state and federal efforts to address occupational illnesses related to pesticide exposures.</p>

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	<p>Collecting occupational monitoring data, developing and refining monitoring techniques, and utilizing this information in an iterative process with public health programs can create public health benefits. Linda Rudolph et al., <u>Integrating Occupational Health Services and Occupational Prevention Services</u>, 40 AM. J. INDUSTRIAL MED. 307 (2001). Such public health benefits extend throughout the development of human life, from the point of conception to old age. Medical monitoring may also provide benefits to families and communities by reducing incidents of suicide and other adverse impacts that related to pesticide exposures.</p>	<p>The APA focuses on the specific directives of the statute being implemented, in this case the WISHAct. In that context, it is appropriate to focus on those benefits that derive from the occupational safety and health context. In addition, the record includes suggestions that a shift in pesticide application practice could in some context be a cost. The department has concluded that the effects of such a shift should be considered neither a cost nor a benefit of this rule.</p>
5.27	<p>L&amp;I Failed To Provide Any Support For Its Dismissal Of Record Evidence Describing The Benefits Related To The Rule's Promotion Of Profitable, Environmentally Beneficial, And Public-Health Protective Alternatives To Using Covered Pesticides</p> <p>L&amp;I refused to consider a host of benefits that the medical monitoring rule will create by facilitating an increase in the use of non-pesticide alternatives to covered pesticides. L&amp;I defended its refusal to consider such benefits by stating:</p> <p>Although the record suggests that pesticide use might be affected, L&amp;I does not consider this potential shift to be either a cost or a benefit of the rule. The rule itself does not in any way restrict the use of covered pesticides, provided the monitoring requirements are met. Although there may be some shift in use patterns, the record is inconclusive about whether such a shift would represent, on balance, a benefit or a cost. Therefore, L&amp;I has treated the impact of any such shift as being an essentially neutral one.</p> <p>CBD, at 10.</p>	<p>L&amp;I's statement mischaracterizes the scope of the cost-benefit analysis and ignores the record evidence that supports inclusion of these benefits in this analysis. Washington's APA requires that L&amp;I "determine that the</p>

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	<p>probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.” RCW 34.05.328. Therefore, the statute requires L&amp;I to consider a broad range of indirect “probable” benefits, not just benefits directly related to a specific requirement of the rule.</p> <p>A wide variety of direct and indirect benefits will inure from the implementation of the medical monitoring rule. (Section C. 1. and 2. below and other comments in the record contain information on the breadth of such benefits.) Thus, the record provides ample support for L&amp;I to integrate such benefits into the final CBD.</p>	<p>The final BCD includes increased discussion of these benefits. As stated previously, the APA acknowledges that explicit quantitative data may not be available to an agency when preparing a BCD and therefore allows agencies to utilize “qualitative” as well as “quantitative” data to complete this analysis.</p>
5.28 Benefit To Workers From Investigations	<p>Earthjustice agrees with L&amp;I that the medical monitoring rule will benefit farm workers in ways other than medical removal. L&amp;I emphasized increased enforcement of the Worker Protection Standard (“WPS”) as one such benefit. CBD, at 8-9. Earthjustice urges L&amp;I to quantify these benefits using the number of workers participating in the investigation phase of the rule because they will enjoy tangible health benefits through better compliance with WPS. L&amp;I should also include the benefits to all farm workers who are required to use WPS, since increased L&amp;I enforcement of WPS will have a deterrent effect on future violations. Increased investigation and enforcement will also promote compliance with other labor standards, housing standards, drift limitations, and a host of other protection provided in WAC 296.307 and RCW 49.17. L&amp;I should include these benefits in the CBD.</p>	<p>The final BCD gives increased attention the effects on worker families. However, the department does not find sufficient information the record to accept the conclusion that adoption of this rule will reduce child labor violations.</p>
5.29 Farm Worker Children And Families	<p>A medical monitoring rule can generate benefits to farm worker children and family members by helping to reduce take-home exposures to neurotoxic pesticides. Reductions in exposure to children and family members could occur when L&amp;I investigates compliance with WPS and medical removals.</p>	

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	<p>Similarly, take-home exposures will decline when employers reduce the number of hours that workers handle pesticides. Reducing children's exposure to pesticides will incur particularly high benefits, given the National Academy of Sciences acknowledgement that "[c]ertain populations of children may be more sensitive to the effects of pesticides because of physiological and biochemical factors...include[ing] exposure through farm work or parental occupational exposure and low socioeconomic status." The rule will also aid in reducing other types of exposures that children and farm worker families suffer when growers use pesticides. The rule will also help to reduce labor violations related to farm worker children and increase the quality and quantity of information collected on child labor. The federal government has documented serious problems with child labor violations in the agricultural sector. L&amp;I should integrate the public health, educational, and social benefits of these activities into the CBD.</p>	
5.30	<p>The Rule Will Benefit Consumers—Including Children—Of Fruits And Vegetables Grown With Organophosphate And Carbamate Pesticides</p> <p>A medical monitoring rule will create benefits by reducing exposures that children and farm worker families suffer when they consume fruits and vegetables grown with covered pesticides.</p>	<p>The department does not consider shift in pesticide application practices to be either a benefit or a cost under this rule.</p>
5.31	<p>Increase Access To Healthcare For Farm Workers And Their Families</p> <p>The medical monitoring rule can help to increase farm workers' access to health care. As a recent Washington State Department of Health survey of farm workers noted, many workers do not talk to their doctors about pesticide poisonings. This rule has built-in protections that preserve the confidentiality of such communications, making it more likely that farm workers will seek medical attention for poisonings. Such protections will also benefit children of farm workers who do not receive adequate medical attention. Increased communication with medical providers will create a variety of public health benefits for farm worker communities that L&amp;I should consider in the CBD.</p>	<p>The final BCD gives increased attention to this issue.</p>

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5.32	<p>I would like to enter the attached report "Can Washington Agriculture Get its Groove Back?" made by Dr. Des ORourke at the recent Central Washington Economic Outlook Conference 2003, on October 28, 2003 as supporting evidence showing that mid sized to small family farmers in Washington State are going out of business in significant numbers. As noted in this report the larger farms while facing significant economic challenges, have a definite competitive advantage.</p> <p>Adding costs such as the recent increases in Labor &amp; Industries Industrial Insurance Rates, Unemployment Insurance Rates, the minimum wage, spray buffer costs and the Cholinesterase Medical Monitoring program is contributing to the mid sized to small farmers inability to compete with the larger farm operators, either in state, and nationally plus international farmers of all sizes. The cholinesterase cost figures for small farmers per employee are slightly lower than that for large farmers however, as a percentage of total costs is higher. The small farmer is hurt more financially since their respective profit margins are much lower than the larger farmer. An analysis of the most recent USDA Census (1997) data will show that Washington State farmers numbers are decreasing and the small to mid size family farmer is decreasing at a much faster rate than any other size category.</p> <p>EPA has looked at Cholinesterase medical monitoring and has determined that the cost benefit ratio etc. did not warrant implementation of such a requirement. Until the state has a significant number of actual complaints, efforts to address the issue should emphasize education on the proper use of organophosphates and ensuring that complaints are documented and segregated properly so that PIRT may thoroughly evaluate specific categories of pesticide complaints. Complaint data should be collected and recorded in the PIRT data base in a way that PIRT can quickly and easily identify problem areas that need to be addressed.</p>	<p>The department's determination that the rule is economically feasible is discussed in the main body of the CES.</p> <p>The data on which the rule is based is also discussed in the main body of the CES, as is the relationship to previous EPA determinations.</p> <p>Labor and Industries has failed to demonstrate that there are a significant</p>

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5.33	amount of agricultural organophosphate/carbamates pesticide handler complaints to justify the rule.	The number of employees affected is based on averages using the employer survey, which the department considers the best available evidence on the subject. A wide variation in the number of employees between different businesses does not contradict such an analysis based on the use of averages.
5.34	The Cost Benefit Analysis underestimates the cost of administering the rules, especially on larger orchard operations. It will be necessary for some ranches to hire a person to help track the chemical application record of the applicators, including hours worked applying OP's and Carbamates. Additional administration will be necessary to notify applicators of the need to be tested, to ensure that testing is actually done in a timely manner, and to keep files of the results. The cost of an additional administrative assistant probably around \$20,000 - \$30,000 per year including taxes, equipment and benefits.	The administrative costs in the final BCD have been adjusted to reflect this concern. However, the department is not convinced that the costs are as extensive as suggested here, particularly since pesticide application is already covered by recordkeeping requirements..
5.35	Larger orchardists and some larger row crop growers will need to invest in software development to track pesticide applications involving OP's and Carbamates.	As noted, the final BCD adjusts administrative costs somewhat to reflect these concerns.
5.36	Potatoes are the second largest crop grown in Washington State, with a farm gate value of approximately \$500 million. Washington State accounts for nearly one-third of all potatoes and potato products exported from the U.S., totaling nearly \$500 million in exports from the Ports of Seattle, Portland, and Tacoma in 2001 alone. A study of the economic impacts of the Washington State potato industry shows that potato farming and related processing contributes \$3.01 billion annually to the Washington economy. (David Holland and Hun Ho Yeo, <i>The Economic Impact of the Potato Industry in Washington State</i> (1997). This translates into 27,600 jobs. (Id.) This is significant considering that Washington State has one of the highest unemployment rates in the nation. (See U.S. Dep't of Labor, Bureau of Labor Statistics, January, 2003; <a href="http://www.bls.gov/web/laumstrk.the.">http://www.bls.gov/web/laumstrk.the.</a> )	Currently, the financial health of the Washington potato industry is The Administrative Procedure Act requires consideration of both qualitative and quantitative costs and benefits and the dictates of the statute being implemented (which places a primary value on worker health). To suggest that a BCD cannot be valid if quantitative benefits cannot be identified is inconsistent with both the plain language and the legislative history of the APA. Indeed, the APA allows agencies to use "qualitative" as well as "quantitative" data in determining probable benefits and probable costs.

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	<p>precarious. During the past five years, selling prices for potatoes have been very low, margins are tight, credit is scarce, and losses are mounting for many Washington potato farmers. The Department of Labor and Industries proposed Mandatory Medical Monitoring Rule, (which WSPC views as providing no significant benefit to worker safety; while at the same time being extremely expensive for the industry to implement), has been a particular concern to WSPC's farmer members.</p> <p>The Washington State Potato Commission strongly believes the Department's proposed Cost/Benefit Analysis (CBA) is inadequate to support the underlying Rule. The Department should withdraw this CBA, and rework it to accurately reflect the quantitative benefits of the rule.</p> <p>Having worked extensively on pesticide issues for many years, the WSPC offers these comments based on its experience.</p>	<p>The WSPC is extremely disappointed that L&amp;I does not even <i>attempt</i> to quantify a benefit for this extremely expensive and intrusive rule (see Appendix I). The fact that the Department cannot quantify any benefits from its proposed rule highlights the concerns repeatedly expressed by the agricultural community that there will be no discernable benefits from this rule. L&amp;I's CBA fall short of what is expected of state agencies under the state's Administrative Procedures Act. The Department's limited attempt to justify this rule by claiming "qualitative" benefits alone is simply indefensible.</p>
5.37	<p>The Department has repeatedly refused to consider the "best data available" when promulgating the Mandatory Medical Monitoring Rule and this Cost/Benefit Analysis (see Appendix I). L&amp;I repeatedly references inconclusive studies that were done prior to the Environmental Protection Agency's issuance of the federal Worker Protection Standard in the early 1990's, and prior to label changes agreed to by registrants that were intended to reduce worker exposure. The Department should have commissioned a pilot project to obtain accurate data on the costs and benefits of this rule before it was adopted.</p>	<p>The comment indicates that the department has refused to consider the best data available. However, rather than referencing any such data that the department has disregarded, the comment then indicates that the department should have developed new data. The department is not legally required to search for perfect data or to duplicate studies that already exist. See, <i>Aviation West v. Department of Labor &amp; Industries</i>, 138 Wn.2d 413, 426, 980 P.2d 701 (1999) ("Choosing to not 'reinvent the wheel' and instead relying upon existing ETS studies that are directly on point appears to us to be a reasonable decision, and the Companies cannot point to a case explaining why the Department should not be able to make it. After</p>

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		all, to use an example, assuming that ETS is deleterious to the healthy workers in one state it would defy logic to argue that it does not have the same effect in another.”) The department has concluded it has sufficient data in the record to make a decision regarding the rule, and has based on that decision on the best available data.
5.38	L&I’s estimate, “ that medical monitoring will identify cholinesterase depression requiring medical removal in between 1.2 and 4.8 percent of participating employees, with a central estimate of 3 percent..” appears to be a guess. However, even with that number, L&I is unable to quantify what benefits might accrue from that number of medical removal (see Appendix I). There are no estimates of medical cost savings or worker savings. There are no quantitative estimates of any benefit. The WSPC believes that L&I must quantify the benefits from its’ proposed rule with much greater certainty than is found in the proposed CBA.	The 3 percent is an estimate based on available information. The BCD also includes a low estimate of 1.2 percent and a high estimate of 4.8 percent, acknowledging some level of uncertainty. Furthermore, the BCD identifies and discusses the qualitative benefits that will accrue from medical monitoring, an approach that is sanctioned by the APA, RCW 34.05.328(1)(c).
5.39	It must be emphasized that if the medical removal rate is significantly lower than L&I’s guess of 3 percent, whatever benefits might accrue from this rule will be that much lower. On the other hand, the fixed cost associated with this rule will not decrease. Accordingly, even if L&I claims the rule’s qualitative benefits outweigh its quantitative costs at this time, if the removal rate is lower than L&I’s present guesses when the first year’s data is reviewed, the Department must reassess the value of this rule.	The rule itself requires the department to reassess the rule, in consultation with stakeholders and scientific advisors, based on the data obtained during the first year.  While the rule will require such a reevaluation, which may include reassessment of some issues addressed in the BCD, the Administrative Procedure Act does not require a new BCD to be completed as part of the evaluation process.
6.0		Additionally, L&I must quickly and effectively gather and collate the data it receives from the 50-hour exposure rule so it can make a reasoned decision on whether or not the rule should automatically drop to a 30-hour exposure limit on January 15, 2005. If the data acquired from the 50-hour rule shows that the actual medical removal rate is below the Department’s 3 percent estimate, L&I must rework its’ CBA with the accurate removal rate if it is to meet the requirements of the Administrative Procedures Act
		<b>ALTERNATE PROPOSALS</b>

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6.01	<ol style="list-style-type: none"><li>1. Use current available programs and resources to address the issue.</li><li>2. Farm workers wanting testing have access to Migrant Farm Clinics.</li><li>Payment of their medical services is set by the workers ability to pay.</li><li>3. Labor &amp; Industries develop and provide educational material on value of ChE monitoring and location of Migrant Clinics.</li><li>4. Labor &amp; Industries train and certify personal at the migrant clinic on the ChE testing methods, etc.</li><li>5. Require Ag. Employers to incorporate the Labor &amp; Industries data into employer required pesticide education programs.</li><li>6. WSDA Pesticide applicator licensing requirements include the Labor &amp; Industries educational material.</li><li>7. WSDA Farm Worker Advisory Committee use funding to due outreach using educational material developed by Labor &amp; Industries.</li><li>8. Columbia Legal Services be required to implement an outreach program utilizing the L &amp; I educational information. (Already funded by state and they support medical monitoring for their clients.)</li><li>9. Unemployment Insurance and Industrial Insurance programs be used to address those individuals who need to be removed from the workplace.</li></ol>	<p>The thrust of this proposal is that employees and other regulatory and representative bodies be held responsible for the providing a safe and healthful workplace. The statutory provision of the WISHA being implemented requires the department adopt rules that “provide for the promulgation of health and safety standards and the control of conditions in all work places concerning gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents which shall set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life; any such standards shall require where appropriate the use of protective devices or equipment and for monitoring or measuring any such gases, vapors, dust, or other airborne particles, toxic materials, or harmful physical agents.” In addition, the statute provides that “where appropriate, any such rule shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure.”</p> <p>Monitoring blood cholinesterase levels will detect workplace exposures that contribute to cholinesterase depression. In accordance with the WISH Act, the cholinesterase-monitoring rule is structured so employers are responsible for identifying and controlling hazardous workplace exposures that contribute to employee cholinesterase depression. The department has committed to make efforts to defray the costs of medical testing during 2004</p> <p>The department has committed to provide a model employee training program and provide medical provider education. Requiring certification of health care providers is beyond the department’s authority.</p> <p>The cholinesterase-monitoring rule does not impact Industrial Insurance regulation. Pesticide exposure claims will continue to be adjudicated in the same manner.</p>

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6.02	<p>1. The department will commit to a non-biased evaluation of the first year data. If the data demonstrates that less than 2% of workers who are exposed at the 50-hour level are suffering from work related cholinesterase depression, the threshold should be increased to 60 hours.</p> <p>2. If the first year data demonstrates that 2 - 5% of workers who are exposed at the 50-hour level are suffering from work related cholinesterase depression, the threshold should remain at 50 hours.</p> <p>3. If greater than 5% of workers who are exposed at the 50-hour level are suffering from work related cholinesterase depression, the threshold should be reduced to 30 hours.</p> <p>4. The department must directly pay all medical provider and lab costs.</p> <p>5. For any quarter in which an employer experiences no worker removals due to workplace related cholinesterase depression, the employer should be allowed to deduct all costs spent complying with this regulation from his or her workers' compensation premium.</p>	<p>The department will organize a scientific team to oversee collection and analysis of data collected during 2004 and 2005. The members of the scientific team will be selected from representatives of the University of Washington, Washington State University, as well as other interested members of the academic and scientific communities. The department will review reports from the scientific team and other relevant information and make modifications to the rule as appropriate.</p> <p>As stated above, the department has committed to make efforts to defray the costs of medical testing during 2004. The cholinesterase-monitoring rule does not address issues related to Industrial Insurance and is not intended to have any impact on the Industrial Insurance Process.</p>
6.03	<p>I asked for the Department of Labor &amp; Industries to first do a pilot project before moving ahead with the across-the-board agricultural testing which is going to cost thousands of dollars at the cost of the agricultural employer. And I would just like to end with that, I ask that we first do a pilot project before moving ahead.</p> <p>.....</p> <p>During regulatory negotiations over the last two years, the Washington Growers League has expressed its support for a pilot project on cholinesterase monitoring prior to adoption of a cholinesterase-monitoring rule to determine the coverage and justification of such a regulation. We have supported this because if cholinesterase-monitoring regulations are</p>	<p>Pilot rulemaking was considered and rejected for four reasons. First, pilot rulemaking is discretionary and the process of public rule development meetings and advisory committees was an appropriate and effective alternative. Second, pilot rulemaking is best suited to situations where an agency intends to issue a highly specific, inflexible and experimental regulation and feasibility of compliance is highly uncertain. In this case, the department decided to move ahead with a rule with demonstrated feasibility, based on sound scientific principles and data. L&amp;I concluded that a rule designed in this manner would not benefit from pilot testing. Third, the department decided to incorporate a two-year phase-in period that to allow data collection and analysis. Fourth, the rule incorporates an implementation plan including a scientific team to oversee collection and analysis of data.</p> <p>In the Rios decision the Washington State Supreme Court found the department</p>

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	adopted, they must fit a legitimate need.	<p>had already conducted investigations studying cholinesterase-inhibiting pesticides, and the report of its own team of technical experts had, in light of the most current research, deemed a monitoring program both necessary and doable. The Court therefore concluded that, in failing to act on the request for rulemaking, the department violated RCW 49.17.050(4), which requires the department to “set a standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health.” Further, the Supreme Court specifically directed the Department to initiate rulemaking. The Department did not believe that pilot rulemaking was consistent with the Court’s decision and order.</p> <p>Our rulemaking investigations have concluded that a significant risk of pesticide poisoning exists, a medical monitoring program is an appropriate method to help reduce that risk, and such a program is technologically and economically feasible. An identified benefit of the rule is that the relative uncertainty regarding the number of employees being poisoned can be addressed by a comprehensive medical monitoring rule.</p>
7.0	<b>CLOSED SYSTEMS</b>	<p>L&amp;I exempted time spent using closed systems from counting towards the exposure threshold as an incentive for employers to use closed systems even when they are not required by the label. This exemption is also recognition of the protection provided to handlers when using closed systems. The intent of closed systems is to eliminate handler contact with the concentrated pesticide formulation.</p> <p>EPA’s finding of unacceptable risk, even when engineering controls or maximum PPE is used by handlers, is one element of L&amp;I’s finding of significant risk supporting this rule making.</p>
7.01	We also petition the Department to not allow any exemptions for closed systems and that all hours for mixing and loading count towards the hours of exposure threshold.	
7.02	In its current review of OPs, EPA has found that “in a number of cases, even with maximum personal protective equipment (PPE)...or with engineering controls, such as closed mixing/loading systems... MOEs are still lower than 100 (exceeding the EPA’s level of concern).” If the reduced exposures made possible by closed systems still endanger workers’ health, this is a fact that workers are entitled to know, and L&I must examine.	
7.03	While the California data shows the clear and compelling benefits of	L&I agrees with the commenter and EPA, closed system are one of the available

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	cholinesterase monitoring, it also shows that closed systems are needed as further protection from the very substantial risk of short-term pesticide exposure from highly toxic pesticides during the mixing and loading process.	methods to provide protection to pesticide handlers. This rule applies only to medical monitoring and is not intended to specifically address the use of closed systems (although it does create an incentive for the use of closed systems to mix and load by exempting such handling from the periodic monitoring requirement). Closed systems usage may be the subject of future rulemaking, if the department deems necessary.
7.04	It should also be noted that the U.S. Environmental Protection Agency already requires closed systems for a substantial number of pesticides. L&I is mandated to enforce the use of closed systems for these pesticides. Moreover, L&I currently has rules requiring feasible engineering controls for pesticides that pose a respiratory hazard. See WAC 296-62-07102 (requiring feasible engineering control measures to control occupational diseases caused by breathing air contaminated with harmful fumes, sprays or vapors).	The degree to which current requirements for engineering controls found in the Respiratory Protection (WAC 296-62-07102) and Air Contaminants (WAC 296-62-07501(3)) rules apply to the use of closed systems, enclosed cabs, and other control measures identified by EPA on pesticide labels, is an area for further investigation. Certainly the data collected from this rule will allow a more in depth analysis of handler exposures and whether or not the absence of these controls is a factor in cholinesterase depressions. L&I would pursue discussions with stakeholders on this issue before proceeding with a change in current enforcement practices related to these rules. This rule applies only to medical monitoring and is not intended to address specifically the use of closed systems. Closed systems usage may be the subject of future rulemaking, if the department deems necessary.
7.05	Our union is a signatory to the Agreed Framework which was negotiated between industry and labor advocates this Spring and forwarded to Paul Trause on April 18, 2003. We believe the implementation of a Cholinesterase testing program is an important step to protect Washington farmworkers from overexposure to certain classes of pesticides. We remain concerned, however, that these rules do not go far enough to protect farmworkers.	EPA requires closed systems for pesticides based on the assessment of the exposure risk and reasonable and effective methods to mitigate those risks. Closed systems are one option for pesticide handler protection, prohibiting liquid formulations and hand held spray equipment are examples of other options EPA utilizes.

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7.06	<p>It is disappointing to see that L&amp;I has failed to include a requirement for closed systems in the proposed rule. Ample evidence has been provided to the agency establishing the need for and feasibility of requiring closed systems. The Rios decision makes it clear that L&amp;I is obligated to keep adding protections against pesticides for farm workers as long as these protections are feasible and they continue to reduce health risks. That standard has clearly been met with respect to closed systems.</p> <p>L&amp;I prepared draft language mandating closed systems and solicited input from stakeholders on that language and on the concept of mandating closed systems. It is inexplicable and inexcusable that the agency is failing to require this necessary and feasible protection, particularly as it goes hand in hand with the monitoring requirements established by the draft rule.</p> <p>Under new federal requirements, L&amp;I will be obligated to enforce closed system requirements for various pesticides widely used in Washington State. It makes little sense and will be confusing to inspectors, to growers, and to farmers for L&amp;I to enforce those requirements for some highly toxic pesticides, but not for others. This is particularly true given the fact that equipment purchased for one pesticide can easily be used for others.</p>	<p>The Supreme Court ordered L&amp;I “to initiate rulemaking on a mandatory cholinesterase monitoring program for agricultural pesticide handlers.” The court did not review the issue of closed systems and the use of closed systems is not included in the Court’s final recommendations. Regardless of the absence of a discussion of closed systems in the Court’s decision, L&amp;I recognizes the benefit of closed systems in the rule by including an incentive for the use of closed systems in relation to cholinesterase monitoring. Any requirement to use closed systems is outside of the scope of the cholinesterase-monitoring rule. Closed systems usage may be the subject of future rulemaking, if the department deems necessary.</p>
7.07	<p>WSDA must cooperate to adopt rules requiring closed systems in conformity with WISHA. RCW 49.17.270 provides, in pertinent part:</p> <p style="padding-left: 2em;">The department [of L&amp;I] shall be the sole and paramount administrative agency responsible for the administration of the provisions of this chapter, and any other agency of the state...having administrative authority over...any regulatory or enforcement authority of safety and health standards related to the health and safety of employees in any work place subject to [WISHA], shall be required, notwithstanding any statute to the contrary, to exercise such authority as provided in this chapter and subject to interagency agreement . . .</p> <p>(Emphasis added.)</p> <p>Section 270 therefore provides that WSDA must cooperate fully</p>	<p>Contrary to the commenter’s belief, the purpose underlying RCW 49.17.270 is to ensure that WISHA standards are enforced in a manner consistent with Chapter 49.17 RCW. There is no explicit requirement set forth in RCW 49.17.270 requiring WISHA to include WSDA in the current rulemaking process. Furthermore, RCW 49.17.270 would merely require WSDA to enforce any cholinesterase monitoring standards that they may have adopted in a manner consistent with WISHA enforcement and the requirements of Chapter 49.17 RCW.</p> <p>RCW 49.17.280(3) governs inspections and the issuance of citations and provides the WISHA and WSDA must cooperate in such inspections and must ensure that they do not issue duplicate citations. This statutory provision does not require WISHA to include WSDA in the current rulemaking process nor does it require the issuance of identical cholinesterase monitoring rules.</p>

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	<p>with L&amp;I in adopting rules that comply with WISHA, if section 280 (RCW 49.17.280) applies to closed mixing and loading systems. Section 280(3) confirms that the requirement for interagency coordination in pesticide rulemaking shall not dilute the protection afforded to all workers under WISHA. The Legislature required that L&amp;I and WSDA enter into an agreement on the WPS that “provides for protection of workers and enforcement of standards that is at least as effective as provided to all workers under [WISHA].” RCW 49.17.280(3).</p> <p>For the above reasons, and those stated in our Petition for Rulemaking and previous correspondence, L&amp;I should require closed mixing and loading systems for all Category 1 and 2 pesticides in liquid formulations or liquid mixes. This requirement should be included in the current rulemaking.</p>	<p>The required use of closed systems for mixing and loading category I and II pesticides is beyond the scope of this rule.</p>
8.0	<p><b>MEDICAL MONITORING</b></p> <p>During the advisory committee discussions L &amp; I and DOH mentioned concern over physician health care provider qualifications and laboratory reliability. One of the answers to those concerns was that L&amp;I stated that they would establish physician, health care guidelines to ensure potential for reliable test results. No such guidelines are mentioned for laboratories in the current rule. What happened to the list of certified laboratories?</p>	<p>The department has committed to develop and distribute guidelines regarding cholinesterase monitoring medical supervision and laboratory testing procedures. These guidelines and operating procedures are being developed in conjunction with physicians and scientists from the University of Washington and the department of Health Public Health Laboratory.</p> <p>The rule requires that employers identify a physician or other licensed health care provider who will provide baseline and periodic cholinesterase testing through a laboratory approved by the department to provide cholinesterase testing. During 2004 and 2005 all laboratory testing will be performed by the department of Health Public Health Laboratory using a standardized testing protocol. Starting in 2006 the department will begin approval of additional laboratories meeting specified cholinesterase-testing standards. Approved laboratories will be posted on the WISHA web site.</p>
8.02	<p>There is no guarantee that medical facilities can meet a standardized protocol for laboratory analysis.</p>	<p>During 2004 and 2005 all laboratory testing will be performed by the department of Health Public Health Laboratory using a standardized testing protocol. Starting in 2006 the department will begin approval of private laboratories that specified</p>

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8.03	The department has not addressed technical problems, which render medical monitoring not feasible at present.	<p>cholinesterase-testing standards.</p> <p>California reviewed cholinesterase test results reported from 1982-1990. This review showed that cholinesterase test results were inconsistently reported due to the use of multiple laboratories, various test procedures, equipment and reporting units. These findings led to the development of cholinesterase test standardization regulations. In addition, California supports a voluntary proficiency-testing program for approved laboratories.</p>
8.04	Abnormal results come from a variety of places, but the most obvious is that the testing is notoriously inaccurate. Dr. Steve Smith, M.D., M.P.H. found variations in excess of 20% - using the same blood and from the same lab. Smith also documented that firefighters with no exposure to organophosphates received reports of depressions in the neighborhood of 30% from baseline. After investigation, he found no reason for the depression, other than inaccurate tests. Dr. Smith explains it this way: This [variations of 20 - 30%] isn't really unexpected when it's understood that the main use of these tests is to document serious acute exposure as would be seen in the emergency department of our hospitals. When a RCB-ChE come back way below normal or even zero, it doesn't require a real accurate test. Dr. Smith's observations explain the data from California - relatively large numbers if abnormal tests but very little real exposure.	<p>The cholinesterase-monitoring rule requires employers to use laboratories approved by the department. All approved laboratories will be required to utilize a specified testing methodology validated by the Washington State Department Of Health Public Health Laboratory. During 2004 and 2005 all cholinesterase testing will be performed by the Public Health Laboratory. After 2005 the Public Health laboratory will act as the reference laboratory for other laboratories approved by the department. This system will ensure that technical difficulties inherent in a large medical surveillance program are minimized to the extent feasible.</p> <p>Cholinesterase laboratory testing techniques have been available since the 1950's. There are a variety of accurate and reliable methods that can be used measure blood cholinesterase activity levels. These include, radiometric (Johnson and Russell), pH (Michel), and thiol substrate (Elman) methods. Difficulties may occur when different methods and variations of methods are used to follow an individual's cholinesterase levels. Studies have demonstrated that carefully run population surveillance programs can be performed with reliable results. In fact the United states military utilizes a cholinesterase blood-monitoring program to monitor employee exposure to nerve agents. The success of any cholinesterase monitoring program rests on rests on standardization of procedures and testing methodology.</p>
8.05	The Medical use of cholinesterase is quite questionable. The effectiveness of the test and there is only one that has proven itself reliable to my knowledge and that is the one the military uses. Can be fooled by time and the	<p>It is correct that cholinesterase tests are not routinely ordered to diagnose acute pesticide poisoning. Most cases of pesticide exposure that present for medical care are acute in nature and symptoms are apparent. Empiric diagnosis (recent</p>

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	individual 1. Cholinesterase I agree is a protein the body manufactures and such the levels can change rapidly and for this reason hospitals cannot and will not rely on it for treatment of pesticide poisoning.	pesticide exposure and the presence of associated symptoms) is sufficient to establish pesticide exposure related illness. Blood cholinesterase depression does not always correlate with acute exposure and in many cases symptoms are associated with other systems (eye, skin, or respiratory tract). Blood-cholinesterase monitoring may be useful as a tool to monitor recovery from acute exposure but is not necessary and is not always done due to a variety of practical reasons, (cost, patient availability, treatment/recovery is not dependent on cholinesterase recovery, etc.)
8.06	<p>... has a concern about the capacity and ability of laboratories to handle the volume of testing that will be necessary for our industry.</p> <ul style="list-style-type: none"><li>• The department must ensure that there is enough lab capacity in the state before enforcing these regulations.</li><li>• It is critical that the department publishes and promotes a list of certified labs.</li><li>• It is also critical that the department establishes one certified lab procedure to maximize test result consistency.</li></ul>	<p>Measuring blood cholinesterase levels is most useful in monitoring chronic, low-level exposure to cholinesterase inhibiting pesticides. Significant depressions in blood cholinesterase levels signal the potential for illness to occur. At that employees can be removed from further exposure and corrections can be made to avoid further exposure thereby preventing systemic illness.</p> <p>The department conducted an employer survey that determines the probable impacts of the cholinesterase monitoring rule. The survey results indicates that approximately 1100 employees will be covered by the medical monitoring requirements in 2004 and 3000 employees will be covered in 2005. A reasonable assumption is that 85 percent of covered employees will elect to participate in cholinesterase testing.</p> <p>At present, the Washington State Laboratory Quality Assurance Office reports that 3 laboratories (2 in Seattle and 1 in Spokane) are approved to perform cholinesterase testing in State. This does not indicate a lack of capacity, even though laboratories are not routinely performing cholinesterase testing in Washington State all laboratories have the capacity to provide cholinesterase testing services through out-of-state reference laboratories.</p> <p>During the first two years of rule implementation all testing will be conducted by the Washington State Department of Health Public Health Laboratory, which has the capacity to process large numbers of tests. The Ellman Laboratory testing</p>

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		method as utilized by Dr. Barry Wilson's cholinesterase testing laboratory at UC Davis will be the standardized testing method used in Washington. Beginning in 2006, capacity will be expanded by opening testing up to other laboratories that meet the department's approval process.
8.07	I'm concerned about the inclusion of carbamates even though they're being lumped into organophosphates. Because of the very fast residual breakdown, we believe that that may be an incorrect inclusion because carbamates are dramatically different in how they react in the bloodstream.	Organophosphate and N-methyl-carbamate pesticides share a similar mechanism of toxicity in that they both bind the Acetylcholinesterase. Because of the weakness of the carbamate-cholinesterase bond the toxic effects of carbamate exposure are generally short lived, in the range of hours to days. This puts the utility of monitoring cholinesterase levels on a 30-day schedule in question. Generally, monitoring at such extended intervals would not be an effective means of monitoring for exposure to N-methyl-carbamate pesticides. Because of this the rule provides for an exemption from cholinesterase testing of those employees whose only exposure is handling N-methyl carbamate pesticides.
		However, because organophosphate and N-methyl-carbamate pesticides share a common method of toxicity, dual exposure to the pesticides may result in an additive effect. Pushing cholinesterase levels down further than would be expected if the exposure threshold was only limited to those hours handling organophosphate pesticides. As cholinesterase levels decrease the potential for cholinergic poisoning increases. Therefore it is appropriate to include dual organophosphate, n-methyl-carbamate exposure when determining exposure thresholds.
8.08	There does not appear to be enough medical provider facilities around the state to accommodate the number of individuals who may need the monitoring service. Forcing the burden of training the medical provider or ensuring their twining onto the employer is unacceptable. This is L&I's responsibility and they should be required to notify employers of doctors who are approved.	The department has identified health care providers in effected geographic areas. Education opportunities will be provided to health care providers and the names and addresses of providers who have completed training will be posted on the WISHA web site. Initial training opportunities will be proved in December and continue through the winter and spring.
8.09	...many studies and empirical observations have demonstrates that the testing is unreliable and there will be many cases of apparent ChE depression that will turn out to be unrelated to pesticide exposure at work.	The reliability of cholinesterase laboratory testing is well established (Kreiger, R.I.(2001). Handbook of Pesticide Toxicology). The misunderstanding regarding laboratory testing reliability and false depressions is related to the use of laboratory normal values to determine cholinesterase depression. Cholinesterase

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		<p>tests without comparative baseline measurements are not independently considered a valid indication of cholinergic depression.</p> <p>In regards to exposures occurring outside of work and the impact on rule promulgation. Monitoring blood cholinesterase levels will detect workplace exposures that contribute to cholinesterase depression. The cholinesterase-monitoring rule is structured so employers are responsible only for reducing hazardous workplace exposures that contribute to employee cholinesterase depression. While non-workplace exposures to the pesticides covered by the rule may occur, the rule does not regulate these non-workplace exposures. . So long as a WISHA regulation addresses workplace hazards, and limits employer abatement to workplace conditions, intervention is appropriate. Even in situations where there is a synergistic relationship between work and non-work exposures (e.g. asbestos and tobacco smoke), the agency still has good reason and a duty to regulate the workplace contribution to risk.</p>
8.10		<p>Medical facilities and providers are available throughout Washington State. In the geographic areas most likely to be impacted by the cholinesterase-monitoring rule there are clinics and other medical services that specifically provide services to the Hispanic and immigrant farmworker populations. Most growers that use toxicity category I and II pesticides already have a relationship with a medical provider to provide medical for employees that use respirators.</p> <p>Even though the department is providing education opportunities and materials to medical providers there is no requirement that employers use a provider that has completed department provided education.</p>
9.0	<b>SPECIFIC WAC SECTIONS</b> <ul style="list-style-type: none"> <li><b>WAC 296-307-148, Scope and summary</b></li> </ul>	<p>The draft rule uses phrases such as “your responsibility” and “you must” at the beginning of most sections. We believe that this terminology is</p> <p><b>No change in rule</b></p>

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	confusing to readers who are not employers. The rules should be understandable to workers, medical providers, and others. We suggest that you replace these phrases with “the employer’s responsibility” and “the employer must.”	The heading directives “your responsibility” and “you must” are standard terminology used in the department’s Clear Rule Writing Initiative. Occupational safety and health regulation provides direction to employers in regards to their responsibilities in maintaining a safe and healthful workplace. It is unnecessary to repeatedly state that it is the employer’s responsibility to comply with occupational safety and health regulation.
9.02	My additional comment is that the workers covered by the regulation also include those who are not engaged in agriculture and are involved with the handling of cholinesterase-depressing pesticides. In other words, all workers who are involved with the handling of cholinesterase-depressing pesticides ought to be required to undergo blood level cholinesterase monitoring. Such workers may include those who maintain landscaped grounds and those who conduct structural pest control.	<p>The effectiveness of the department’s rule format has been repeatedly verified through user usability testing. The department believes that it would be confusing to employers and employees if rules were written in different formats.</p> <p><b>No change in rule</b></p> <p>The evidence suggests that agricultural pesticide handlers are at significant risk. In the <i>Rios</i> decision the Washington State Supreme court directed the department to “to initiate rulemaking on a mandatory cholinesterase monitoring program for agricultural pesticide handlers...” This decision was based on a weight of evidence approach that indicated that agricultural workers who handle category I or II cholinesterase inhibiting pesticides face material impairment of health.</p> <p>Whether or not workers in other industries face equal exposure hazards has not been thoroughly investigated. The department has asked for evidence showing a significant hazard in industries other than agriculture and has not received evidence indicating that it is appropriate to include other industries within the scope of this rule.</p>
9.03	<b>WAC 296-307-14805, Maintain handling records for covered pesticides</b> Accuracy of records is critical to the success of the monitoring program. Farm workers, growers, researchers and policy makers need to know precisely what we are measuring. This becomes all the more important given that there are different hour thresholds in 2004 and 2005. Given this we would suggest that the Department require a standardized reporting form.	<p><b>No change in rule</b></p> <p>The cholinesterase-monitoring rule requires that all time that each employee spends handling category I or II organophosphate or N-methyl-carbamate pesticides be documented. Documentation would include all handling activities defined in the WAC 206-307-11005. Sample documentation forms are included in</p>

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9.04	The rule should also require that when an employee's test results reach thresholds mandating a workplace investigation or removal of that employee, the employer must provide L&I with copies of the handling records concerning the handling activities of that employee for the 60 days prior to the test.	<p>the Helpful Tools Section of the rule. These forms can be used to meet all of the handling documentation requirements in WAC 296-307-14805.</p> <p><b>No change in rule</b></p> <p>The department believes that requiring employers to provide the department with all handling records of employee's who have experienced significant cholinesterase depressions would be an undue burden to employers. Employers are already required to maintain these records for seven years and to provide these records to the department upon request. This information can be obtained by the department through routine inspection procedures.</p>
9.05	Requires employers to keep records of all time each employee spends handling covered pesticides, including those employees who would not be expected to meet the threshold to require testing. This places an undo burden on employers for no apparent reason. If an employee occasionally helps unload a truck, record keeping should not be required. Only those employees who, based on their job duties, would reasonably be expected to come close to meeting the threshold should be subject to record keeping.	<p><b>No change in rule</b></p> <p>Pesticide handling activities have been identified as those activities that carry the highest risk of exposure to individuals working with agricultural pesticides. Therefore it is appropriate to include all handling activities under the scope of the rule. Unloading closed pesticide containers from a truck would not be an activity included in the definition of "handling" and therefore employers would not be required to document the time spent in such activities.</p>
9.06	...The section should... specify that employers must assign identification numbers for each employee in accordance with a system designed by L&I which will enable L&I and others to: 1) link lab test results for each individual employee to his or her handling data, 2) track the total number of hours that each individual employee handles OPs and CBs, and 3) link lab test results for employees to specific employers so that L&I and evaluators can identify which farms and orchards warrant attention in order to protect workers. The rule should require that employers ensure that medical supervisors and laboratories have and use the identification number for individual farm workers who receive cholinesterase testing.	<p><b>No change in rule</b></p> <p>Creating and managing an identification system for all covered agricultural workers is beyond the scope of this rule and the capabilities of the department. Even though this idea on its basis may appear to be an efficient way to track and match test results and other information with employees and employers, it is fraught with implications that could illicit legal challenge. The department feels that the best approach to tracking and matching cholinesterase tests is to utilize the public health surveillance process provided in WAC 246-101-001, Notifiable Conditions. The department of Health Laboratory and Epidemiology office will be responsible for matching employees and test results.</p> <p>A sample documentation form will be provided as a Helpful Tool that will meet all of the documentation requirements of this section. In addition the definition of</p>

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9.07	<p>Language should be added to ensure that laboratories submit test results (using the above-mentioned identifier numbers) to the L&amp;I central database. It will be impossible for L&amp;I to ensure compliance with the cholinesterase rule if laboratories do not do this. It will also be impossible for academic institutions and others to evaluate the monitoring program and its results. Yet there is no legally enforceable mandate in the draft rule to ensure that this happens. Options to correct this oversight include: i) expressly mandating that labs report test results, if doing so is within L&amp;I's jurisdiction and/or ii) requiring that employers ensure that the labs to which samples are sent report the data to L&amp;I.</p>	<p>handler will be included on the back of this form.</p> <p><b>No change in rule</b></p> <p>The department will work with the Public Health Laboratory to develop a cholinesterase testing laboratory requisition form. Use of this form will be included in the laboratory's Standing Operating Procedures for Cholinesterase Blood Testing. Use of a standardized laboratory requisition form is not an employer or employee responsibility and therefore not a condition of the cholinesterase monitoring rule.</p>
9.08	<p>In new section WAC 296-307-14805 the text reads "You Must: Maintain accurate records of all time that each employee spends handling category I or II organophosphate or N-Methyl-carbamate pesticides..." I request that the department add language here that says: "OR employers can simply test all handlers that meet the handling hour thresholds". OR "employers must accurately track all time of each handler that the employer estimates will surpass the 50/30 hour threshold."</p>	<p><b>No change in rule</b></p> <p>Employers are asked to make a reasonable determination of which employees will meet or exceed the exposure thresholds during the upcoming pesticide application season. The department feels that it is reasonable to expect that the employer will be able to make an accurate determination based on knowledge and past pesticide use patterns and experiences. At the same time the department recognizes that accurate determinations will not or cannot be always made. Documenting handling hours for all employees handling covered pesticides is necessary in order for employers to adequately track employee exposure hours and for the department to assess compliance with the requirements of the rule.</p> <p>In addition, for purposes of evaluating the rule during 2004 and 2005 it is imperative that the department have access to information that will allow for a valid determination of the rule benefits and when necessary to make modifications to the rule based on the best available data.</p>
9.09	<p>The proposed rule states under "Helpful tool" that L&amp;I will supply a sample documentation form. This is not sufficient. The rule should precisely state the type of information that the employer must keep. For example, WAC 296-307-14505 specifies nine types of information that must be retained for pesticide applications.</p>	<p><b>No change in rule</b></p> <p>The cholinesterase-monitoring rule requires that all time that each employee spends handling covered pesticides be documented. All "handling" activities are already defined in WAC 296-307-11005. It is not necessary to repeat the</p>

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Issue Number	Typical Comments or Typical Point(s)	Response
9.10	Department clarification	<p>definition here. A sample documentation form will be provided as a Helpful Tool that will meet all of the documentation requirements of this section. In addition the definition of handler will be included on the back of this form.</p> <p><b>Rule change</b></p> <p>The department thought that it was important to clarify the physician's or licensed health care professionals ability to access handling records in order to appropriately evaluate employees exposure risks. WAC 296-307-14805 has been amended to read:</p> <p>- <i>Make sure that pesticide-handling records are readily accessible to employees, their designated representatives, and treating health care professionals.</i></p>
9.11	<b>WAC 296-307-14810 Implement a medical monitoring program.</b>	<p><b>No change in rule</b></p> <p>The current cholinesterase monitoring recommendation states that testing should be provided when employees handle toxicity category I or II organophosphate and N-methyl-carbamate pesticides for 30 or more hours in any consecutive 30-day period.</p> <p>The department has decided that the 30-hour exposure threshold in the cholinesterase monitoring recommendation is appropriate. No evidence has been provided that would indicate that this exposure threshold should be changed. Despite this, the general consensus of grower stakeholder representatives was that the exposure threshold should be higher. The department and worker stakeholder representatives agreed to increase the exposure threshold to handling covered pesticides for 50 or more hours in any consecutive 30 day period as a means to mitigate initial impacts on growers during the first year of rule adoption. Beginning in the second year the exposure threshold will return to handling covered pesticides for 30 or more hours in any consecutive 30-day period. However, the rule allows for evaluations to occur at the end of the first and second years and for modifications to occur as necessary based on the evidence gathered.</p>
9.12	We also found the proposed schedule for testing arbitrary and confusing.	<b>No change in rule</b>

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	<p>There is no reason that employers should be allowed to wait thirty days for the initial baseline test once a worker reaches the hourly threshold. Agricultural employers engage in careful planning and will be able to anticipate when a class of their employers will reach the required threshold for testing.</p> <p>Part of that planning process should include the prompt establishment of a baseline. We believe thirty days is too long, and propose employers have three days to provide testing. A shorter interval will also facilitate farmworker participation to ensure compliance with the rules.</p>	<p>To establish a valid baseline test the worker must not have handled covered pesticides for at least the preceding 30 days. Baseline cholinesterase levels are established during the winter or early spring months prior to the start of the pesticide application season and not established after the worker has begun handling covered pesticides or has reached the exposure threshold limit.</p>
9.13	<p>Add: If the scientific work group and advisory committee established under this rule, determines the 2004 data shows no benefit to worker health and/or safety, then Labor &amp; Industries will raise the threshold to 70 hours. If the data supports lowering the threshold, the threshold will be lowered to 30 hours in January 1, 2005. (Note: At present there is no scientific justification for any of the threshold mentioned.)</p>	<p><b>No change in rule</b></p> <p>The current cholinesterase monitoring recommendation states that testing should be provided when employees handle toxicity category I or II organophosphate and N-methyl-carbamate pesticides for 30 or more hours in any given 30-day period. The department has decided that the 30-hour exposure threshold in the cholinesterase monitoring recommendation is appropriate. No evidence has been provided that would indicate that this exposure threshold should be changed.</p> <p>The use of a 50-hour exposure threshold in 2004 is provided as an initial rule mitigation. In 2005 the exposure threshold will move to the set 30-hour threshold. The rule contains language that states “The department will adjust the threshold for medical monitoring of employees under this rule on February 1, 2005, if the data collected during 2004 clearly demonstrates that the threshold should be either lower or higher than thirty hours.” This approach was agreed upon by representatives of agricultural employers, employees and legislators.</p> <p><b>No change in rule</b></p>
9.14	<p>We would also petition that the hours for mixing and loading and using closed systems be counted as part of the 50 and 30 hours, as well.</p>	<p>The rule includes an exemption from counting the hours spent mixing and loading using closed systems, as an incentive for employers to increase the use of closed systems for pesticide mixing/loading applications. The benefit from an increased use of closed systems would be a reduction of accidental splash/spill exposures and medical removal partly or wholly due to these types of exposures.</p>

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Issue Number	Typical Comments or Typical Point(s)	Response
9.15	<b>WAC 296-307-14815 Identify a physician or licensed health care professional.</b>  ...the employer should be required to identify a physician or other licensed health care provider (LHCP) who has participated in training on cholinesterase monitoring for medical supervisors to provide the cholinesterase testing, interpretation of test results, and recommendations. The employer should not be allowed to use the services of an untrained, unqualified provider. It will not be difficult to identify a trained provider because L&I will publish a list of trained providers on the internet.	<b>No change in rule</b>  Certification of medical providers or determining competency to provide services is outside of the authority of the department and outside of the scope of the cholinesterase-monitoring rule. The department considers that medical providers are competent to provide all services permitted under the scope of licensure.  The department will provide education and resource materials to medical providers and maintain a list of medical providers who have completed department provided training.
9.16	L&I's Small Business Economic Impact Statement (SBEIS) states that the rule addresses the problem of variability of cholinesterase test results due to different laboratory methods "by requiring that the same laboratory using the same method analyze each individual's baseline and periodic tests." SBEIS at 4. But the proposed rule does not include this requirement. L&I should correct this omission by requiring that the baseline and periodic tests be performed by the same laboratory wherever feasible. All laboratories should be required to use the Ellman method because experience has shown that method to be the most reliable.	<b>No change in rule</b>  The final rule does not include a requirement that "baseline and periodic tests be performed by the same laboratory wherever feasible." The Department believes that requiring the use of an approved laboratory using the approved testing to account for testing variability. This is even less important considering that all cholinesterase testing will be performed through the Public Health Laboratory during the initial two year rule evaluation period.
9.17	Due to the fact that L & I recognizes that the cholinesterase levels can be lowered by a number of things other than organophosphates and/or carbamates, the following statement should be added: The Washington State Department of Labor and Industries will provide the physician or other licensed health care provider (LHCP) with a list of elements that lower cholinesterase levels (other than OP's and carbamates) so that the health care provider may ask the patient if he/she has been exposed to those identified elements.	<b>No change in rule</b>  The department agrees that this information is important for medical providers to have in order to accurately evaluate the cause(s) of cholinesterase depression. This information will be included in the medical provider education materials. It is not necessary to include this specific information in the rule.
9.18	The rule should not go into effect until adequate numbers of physicians and LHCPs are trained and adequate numbers of laboratories are approved in appropriate areas of the state to facilitate easy compliance with the rule.	<b>No change in rule</b>  Licensed health care providers are permitted to provide medical services as

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		<p>defined by scope of licensure. Certification of medical providers or determining competency to provide services is outside of the authority of the department and outside of the scope of the cholinesterase-monitoring rule.</p> <p>There are adequate medical resources available in all affected areas of the state. The department has identified occupational health services, family medical practices, and community clinics that currently provide medical services to growers, farmworkers, and their communities (Hoffman, J. Memorandum, October 1, 2003 and October 9, 2003). Cholinesterase-monitoring workshops for medical providers will be provided prior to and after the February 1, 2004 rule effective date. All providers participating in a workshop will be listed on the WISHA web page.</p> <p>Employers are not required to contract for services with a physician or licensed health care provider that has completed department required training. In fact, the department anticipates that most employers will simply use the medical providers that they already contract with to provide such services as required medical evaluations for the use of respirators.</p> <p>The department has arranged for all agricultural, occupational cholinesterase testing in 2004 and 2005 to be conducted through the Department of Health Public Health Laboratory. This provides a variety of advantages including, but not limited to, use of an experienced laboratory, consistent laboratory testing methodology and equipment, standardized reporting of results, and enhanced surveillance capabilities. In 2006 laboratory resources will be expanded to include private laboratories approved by the department to provide cholinesterase testing.</p>
9.19	Department clarification	<p><b>Rule change</b></p> <p>The department thought that it would be beneficial to clarify the Department of Health's public Health Laboratory as the sole approved laboratory for the years 2004 and 2005 and to clarify the written recommendations and opinions provided</p>

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Issue Number	Typical Comments or Typical Point(s)	Response
		<p>to the employer by the LHCP. WAC 296-307 14815 has been amended to read:</p> <ul style="list-style-type: none"> <li>• <i>Identify a physician or other licensed health care professional (LHCP) who will:</i> <ul style="list-style-type: none"> <li>– <i>Provide baseline and periodic cholinesterase testing through the department of health public health laboratory, or beginning in 2006, through any laboratory approved by the department of labor and industries.</i></li> <li>– <i>Interpret tests.</i></li> <li>– <i>Provide you with written recommendations and opinions that:</i> <ul style="list-style-type: none"> <li>▪ <i>Identify employees with periodic test results requiring a work practice evaluation.</i></li> <li>▪ <i>Identify employees with periodic test results indicating they must be removed from handling and other exposure to organophosphate and N-methyl-carbamate pesticides.</i></li> <li>▪ <i>Provide guidance on medical monitoring</i></li> <li>▪ <i>Include any other relevant information concerning an employee's workplace exposure to organophosphate and N-methyl-carbamate pesticides.</i></li> </ul> </li> <li>• <i>Instruct the physician or other licensed health care professional (LHCP) to NOT reveal in writing or in any other communication with you, personally identifiable medical information, other than laboratory test results, for any employee.</i></li> </ul> </li> </ul>
9.20	Department clarification	<p><b>Rule change</b></p> <p>The department felt that it was misleading to direct employers to “obtain” copies of employee test results. The employer is required to ensure that these records are maintained in a confidential manner for seven years. The contracted physician or other licensed health care provider will do this for the employer. WAC 296-307-14815 has been amended to read:</p>

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Issue Number	Typical Comments or Typical Point(s)	Response
		<ul style="list-style-type: none"> <li>• <i>Make sure copies of employee test results and written recommendations from the physician or LHC/P are maintained for seven years.</i></li> </ul>
9.21	<p><b>WAC 296-307-14820 Make cholinesterase testing available.</b></p> <p>Though we would have preferred that all workers be medically monitored, that there be no opt out provision, we reluctantly agreed to a declination process (article 3 of the agreement) on the condition that the choice be made through the primary relationship between the worker and the medical supervisor. In addition any interference by the grower or his/her representative would constitute unlawful discrimination (article 4 of the agreement). In the note to this section the word “may” ought to be replaced with the word “shall” to be consistent with the labor/grower agreement.</p>	<p><b>No change in rule</b></p> <p>Including a predetermination of unlawful discrimination in the rule is not appropriate. Any suspected interference will be investigated on a case by case basis. The fact that agreements have been made between various stakeholder groups does not override the statutory authority of the department under RCW 49.17.160 to investigate each claim of discrimination as appropriate.</p>
9.22	<p>Schedule for periodic testing: The initial cholinesterase test for the season should be required within 3 days after meeting the levels in Table 1. The proposed rule allows the employer to wait 30 days to provide the test, even if the worker meets the 30/50-hour threshold after a few days. The initial cholinesterase test for the season should take place promptly to ensure that safe handling practices are established.</p> <p>After the initial test, periodic testing should occur at intervals determined by the medical supervisor of up to 30 days, as long as the worker continues to meet the threshold for coverage. Guidelines provided to medical supervisors should include factors to consider in establishing the testing interval, including the extent of cholinesterase depression, the hours that the worker spends handling covered pesticides, and the likelihood that delays in testing will create unacceptable gaps between exposures and blood tests.</p>	<p><b>Rule change</b></p> <p>Periodic testing is required no more often than every 30 days. The 30 day requirement begins on the first day of handling covered pesticides. WAC 296-307-14820 has been amended for clarity to state:</p> <ul style="list-style-type: none"> <li>– <i>Provide periodic RBC and plasma cholinesterase testing:</i> <ul style="list-style-type: none"> <li>▪ <i>Within three days after the end of each thirty-day period where the employee meets the handling levels in Table 1; however, testing is not required more often than every thirty days;</i></li> <li><b>OR</b></li> <li>▪ <i>At least every thirty days for those employees who may meet the handling levels in Table 1.</i></li> </ul> </li> </ul> <p><i>Note: The first thirty consecutive day period begins on the first day of handling organophosphate or N-methyl-carbamate pesticides after obtaining the baseline cholinesterase test.</i></p>
9.23	The rule should also require a cholinesterase test within 24 hours whenever the employer has reason to believe that a covered handler has been poisoned or injured by exposures to pesticides on the job. In case of a suspected	<p><b>No change in rule</b></p> <p>The department believes that this is a clinical care decision that is made by the</p>

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	poisoning, the employer should not be allowed to wait up to 30 days to provide a cholinesterase test.	medical provider. WAC 296-307-13005 already requires that whenever there is reason to believe that an employee has been poisoned or injured by exposure to pesticides while on the job, the employer must provide appropriate services. This WAC is referenced in the rule.
9.24	<p>Working baseline: The proposed rule does not define the process for taking a “working baseline.” That process must be defined in the rule. The rule should incorporate the following process set forth in the California Physician Guidelines, at p. 8:</p> <p>[A] “working baseline” should be obtained after the longest practicable exposure-free period available, with notation as to when the last exposure occurred. If this “working baseline” is below “normal or in the low-normal” laboratory range, the worker should be advised to discontinue exposure for at least 30 days, at which time a new exposure-free baseline can be established.</p> <p>The second bullet of the working baseline provision should be clarified as follows:</p> <p>Where a working baseline is obtained, the employer must follow the recommendations of the physician or LHC/P regarding continued employee pesticide handling or removal from handling until a thirty-day exposure free baseline can be established.</p>	<p><b>No change in rule</b></p> <p>The procedures for establishing a “working baseline” are guidelines to medical providers and not employer requirements under the rule. As such, California does not include these guidelines in their Medical Supervision rule but includes the guidelines for obtaining a working baseline in their “Guidelines for Physicians” manual. The department feels that this is appropriate and will include guidelines for obtaining a “working baseline” in the medical provider resource materials.</p>
9.25	We support requiring that the employer obtain the declination form from the medical supervisor, and that the employee may decline participation only after discussing the risks and benefits with the medical supervisor.	<p><b>No change in rule</b></p> <p>It is the employer responsibility to ensure that all requirements of the rule are met. The employer may choose to provide a copy of the signed declination statement, that is obtained from the medical provider, to the employee. Or the employer may contract with the medical provider to provide a copy of the declination statement acting as an agent for the employer.</p>

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9.26	The second exemption under this section is unclear. It should be reworded so that its meaning is understandable.	<p><b>Rule change</b></p> <p>The department agrees, the exemption has been reworded as a note to state</p> <ul style="list-style-type: none"> <li><i>You do not need to count time spent mixing and loading using closed systems (as defined in WAC 296-307-13045 (4)(d)) in determining the need for periodic testing. Time using closed systems is still counted for purposes of establishing coverage under this rule and determining the need for obtaining baseline cholinesterase levels.</i></li> </ul>
9.27	L&I should create an exception to limits on the number of follow-up tests which can be required within a thirty day period for situations in which workers experience health effects potentially associated with OP or CB exposures. Follow-up testing should be required in these situations within a day of the exposure episode that triggered health effects even if this will result in more than one follow-up within a thirty day period. By definition, a worker has potentially been injured or made ill by his or her workplace in this scenario. L&I must ensure that as much as possible is done to assess the workers' health status and to prevent additional health problems. Inconvenience to the grower associated with more frequent testing is clearly outweighed by the need to protect the workers' health in this situation and the rules should reflect this.	<p><b>No change in rule</b></p> <p>WAC 296-307-14825 requires the employer to follow any additional occupational health recommendations from the physician or health care provider. This direction allows the medical provider to order any additional follow-up testing that is deemed necessary to provide appropriate care and treatment to a worker whom experiences significant cholinesterase depression and/or associated illness. WAC 296-307-13005 already requires that whenever there is reason to believe that an employee has been poisoned or injured by exposure to pesticides while on the job, the employer must provide appropriate services. This WAC is referenced in the rule.</p>
9.28	The individual who decides to participate in the testing should be required to sign a form that documents to the participant their understanding that the test result information may be provided to:	<p><b>No change in rule</b></p> <p>Provision of this information is the responsibility of the treating medical provider through the process of obtaining informed consent.</p> <ol style="list-style-type: none"> <li>1. His/her employer.</li> <li>2. His/her designated representative.</li> <li>3. Government agencies for purposes of complying with laws related to worker's compensation or similar programs established by law.</li> <li>4. Law enforcement in response to valid subpoena or other legal process.</li> <li>5. Respond to a court or administrative order.</li> <li>6. Etc. (Not sure who else could legally gain access to the health</li> </ol>

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9.29	<p>information.)</p> <p>The requirement for a worker to be "c counseled" by a doctor before they can refuse to participate is unacceptable. Workers should be able to make this decision without physician coercion.</p>	<p><b>No change in rule</b></p> <p>Medical monitoring is beneficial to the employee. Medical providers are duty bound to act in the best interests of their patients. This includes the responsibility of obtaining informed consent prior to taking action to or on behalf of a patient. Informed consent means that a worker's decisions about a treatment or action plan is made with a clear understanding, including material risks, benefits, and alternative treatments. The purposes of obtaining informed consent include 1) allowing the worker to make an autonomous decision, 2) protecting the worker from harm, and 3) ensuring accountability among health care professionals. In order to be valid, informed consent must have the following characteristics 1) given freely without coercion, and 2) given with full understanding. The department believes that the medical provider is the most appropriate person to provide medical information, answer questions of a medical nature and obtain informed consent from the employee to participate in medical surveillance.</p>
9.30	<p>The department should publicize the option for employees to opt-out of cholinesterase monitoring to pesticide handlers and the medical community.</p>	<p><b>No change in rule</b></p> <p>The option to decline participation in the cholinesterase testing program is clearly stated in the rule and will be included in worker and employer training and outreach materials.</p>
9.31	<p>It says in the rules that employees may decline only after receiving training about Cholinesterase. Who is going to provide that training? And is that going to be a medical doctor? And if it is not going to be a medical doctor, I question the objectivity of the information that's given out, other than if it is in writing; and, if so, are you going to provide that? So I have a question on that, where that material is going to come from and who is going to do it.</p>	<p><b>No change in rule</b></p> <p>The cholinesterase monitoring rule states that the employee may decline cholinesterase testing only after they receive training about cholinesterase inhibiting pesticides and discuss the risks and benefits of participation with the physician or licensed health care provider. Pesticide handler training is already mandated under WAC 296-307-14020, Pesticide safety training. The cholinesterase rule simply requires employers to ensure that this already mandated training is provided prior to the worker making a decision regarding participation</p>

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9.32	We also remain concerned about the potential for employer interference in worker decisions to participate in the testing program. The proposed rule is silent on how farmworkers will be informed of their rights, including that to opt out free of employer coercion. We propose that under Section 14815 that an affirmative statement be included which indicates that; "Eligible employees shall have the right to decide on participating in this program free of any employer interference and that such interference shall, (not may) represent unlawful discrimination." This statement should be again repeated on the Cholinesterase Medical Monitoring Participation Statement listed as Appendix A. Farmworker deserve to know what their rights are under this rule.	<p>in the cholinesterase-testing program. The department will provide a model training program.</p> <p><b>No change in rule</b></p> <p>A statement regarding unlawful discrimination is included in this section. Adding additional statements will serve no apparent purpose.</p> <p>Farmworkers are provided the ability to make the decision as to whether or not to participate in cholinesterase testing in consultation with a health care provider. Employers are removed from this process.</p> <p>Including any predetermination of unlawful discrimination in the rule is not appropriate. Any suspected interference will be investigated on a case by case basis in accordance with RCW 49.17.160.</p>
9.33	Department clarification	<p><b>Rule change</b></p> <p>The department felt that it was necessary to clarify what was meant by a "written declination statement." The department would expect that the employee would sign any declination statement. WAC 296-307-14820 has been amended to read:</p> <ul style="list-style-type: none"><li>• <i>Obtain a signed declination statement from the physician or LHCP for employees who decline cholinesterase testing.</i></li></ul> <p><b>WAC 296-307-14825 Respond to depressed cholinesterase levels.</b></p>

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9.34	The text of the last row, second column of Table 2 should be revised to state: “The employee may return to handling class I and II organophosphate and N-methyl-l-carbamate pesticides if approved by the supervising physician or LCHP.” After removal from exposure, the medical supervisor should specifically approve any return to activities that involve exposure to organophosphate or N-methyl-l-carbamate pesticides.	<b>No change in rule</b> The criteria for returning to handling activities is a test result indicating a cholinesterase level within 20% of the baseline. The physician or LHCP will interpret the test results.
9.35	We support the remainder of this section. We wish to emphasize the importance of removing overexposed employees from “handling and other work exposures to organophosphate and N-methyl-l-carbamate pesticides such as thinning and harvesting in previously treated areas” as provided in the second column in Table 2. The Agreed Framework similarly states that removed workers “may be required to perform work that does not involve handling covered pesticides or other significant exposure to those pesticides.”	<b>No change in rule</b> The department agrees that it is important to avoid all potential work exposures to organophosphate and N-methyl-l-carbamate cholinesterase-inhibiting pesticides until cholinesterase levels have sufficiently rebounded.
9.36	...recommends that the level of plasma ChE depression that triggers a workplace investigation (see Table 2 proposed WAC 296-307-14825) be set at 30% from baseline.	<b>No change in rule</b> The EPA’s Office of Pesticide Programs has found that a difference between pre and post exposure cholinesterase levels of 20% or more is nearly always medically significant and correlates with exposure. Both the World Health Organization and the American Conference of Governmental Industrial Hygienists recommend that individuals be removed from exposure when Acetylcholinesterase levels fall 30% from baseline. The department feels that a 20% drop in either plasma or red blood cell cholinesterase level is an appropriate indicator of exposure and warrants work practice evaluation.
9.37	Department clarification	<b>Rule change</b> The department felt the use of the word “investigate” could be misleading. WAC 296-307-14825 has been amended to read:  - <i>Evaluate the employee's work practices to identify and correct potential sources of exposure</i>

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9.38	Department clarification	<p><b>Rule change</b></p> <p>The department felt it was necessary to emphasize that the employer must follow all recommendations from the physician or other licensed health care provider in regards to medical follow-up of an employee with significant cholinesterase depression. The direction to "Continue cholinesterase monitoring according to the schedule in WAC 296-307-14825" was misleading in that the physician or LHCP may recommend more frequent testing as necessary. WAC 296-307-14825 has been amended to read:</p> <p style="text-align: center;"><i>- Continue periodic cholinesterase monitoring.</i></p>
9.37	<b>WAC 296-307-14830 Provide medical removal protection benefits.</b>	<p>The requirement of medical removal benefits is what allows farm workers to make a real choice for medical monitoring. When a farm worker needs to be medically removed s/he should be covered like any other worker. A six-month threshold is the shortest level we have seen for other workers exposed to toxic chemicals. L&amp;I should increase the medical removal benefits to six months or at least allow for the discretion of the Director to increase the period of time for removal benefits beyond three months as needed.</p> <p>The length of worker protection benefits is determined based on the known toxicologic and physiologic effects of a toxic substance. The length of medical removal benefits provided for one substance has no bearing on the length of benefits provided for another.</p> <p>The only indication for the estimated length of time for a medical removal period that could be found in field studies is an average of 3.5 weeks. In this study the results of data on 100 workers who had ongoing cholinesterase monitoring were evaluated. The shortest time an employee was removed from exposure was 1 day. The longest removal period was 119 days. Removing these outliers from the calculation, it is reasonable to expect a 22-day average removal period. Given this information the department feels that 3 months maximum medical removal protection is appropriate.</p> <p><b>No change in rule</b></p>
9.38	This section should also require growers to report to the Department the names and dates of workers placed on medical removal benefits and when they are taken off of medical removal benefits.	<p>The department feels that this would create an undue burden on employers. This information can be collected by the department during routine inspection activities that will be conducted in response to cholinesterase depressions that reach the work removal level.</p>

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### Select Comments and Responses Summarized by Category or Subject Matter

Issue Number	Typical Comments or Typical Point(s)	Response
9.39	<p>The last bullet of this section should be clarified to read:</p> <p>Provide medical removal protection benefits that include maintenance of the same pay, seniority and other employment rights and benefits of <i>the removed</i> employee as though the employee had not been removed from exposure to organophosphate or N-methyl-carbamate pesticides.</p> <p>There should be an additional bullet in this section stating that if an employer voluntarily removes a worker from exposure or otherwise places limitations on an employee "due to the effects of exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee." See WAC 296-62-0752(1)(2)(b)(vii). This could apply to a situation where an employer transfers an employee to a lower paying job just prior to the employee reaching the threshold for removal.</p>	<p><b>No change in rule</b></p> <p>This section already provides the medical removal benefits outlined. The department believes that rewriting this section as suggested would provide no additional benefits or clarity.</p> <p>The provision of medical removal benefits applies to employees that have been removed from further workplace exposure due to an increased potential for illness or diagnosed illness. Expanding the concept of medical removal benefit to include requiring employers to retain a covered employee's status and benefits outside of the scope of medical removal would be an unfair and possibly illegal infringement on employer rights.</p>
9.40	<p>In advisory group discussions the language used to provide benefits for "up to" a maximum of three months. The individual removed was supposed to be able to return to work when their cholinesterase levels returned to 20 percent of the personal baseline.</p> <p>The current language needs to be clarified by adding the words "up to" a maximum of three months. (Some could misinterpret the current language as requiring a maximum of three months benefits on each occasion). The Small Business Economic Impact Statement for this rule bases its analysis on the fact that medical removal is for "up to three months." (See Page 1, middle of page, and Page 5 bullet point number 11).</p> <p>In order to give guidance to the doctor on this issue of duration of removal, it should be noted on this section that "regeneration (replacement) of permanently bound AChE is measured at the rate that AChE is synthesized in the blood stream (approximately 1% per day)." (Language taken from Small Business Impact Statement and comments from DOH.) Without such guidance the doctor may unnecessarily default to three months in every months in every case, in order to ensure no malpractice etc. problems.</p>	<p><b>No change in rule</b></p> <ol style="list-style-type: none"> <li>1. The current language in the rule is correct in that it allows medical removal benefits to be provided for up to three months on each occasion that an employee is medically removed from exposure to cholinesterase inhibiting pesticides.</li> <li>2. It is not necessary to include information for medical providers regarding the regeneration of cholinesterase in the rule. This information will be included in the education materials and guidelines on cholinesterase monitoring that the Department will make available to medical providers.</li> <li>3. Medical removal protection benefits protect the employee's salary, seniority, and other benefits while the employee has been medically removed from exposure. These protections are to remain intact until the employee returns to handling covered pesticides. The employer may take any necessary corrective actions at that time.</li> </ol>

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### Select Comments and Responses Summarized by Category or Subject Matter

Issue Number	Typical Comments or Typical Point(s)	Response
	<p>A provision should also be added that any participant in the medical monitoring program, who is collecting medical removal protection benefits due depressed Cholinesterase levels, loses those benefits if they become a handler of organophosphates and carbamates for a separate employer during that removal period.</p> <p>Note: Does payment of medical removal benefits by the employer constitute "legal" employment so that an individual could not collect unemployment insurance at the same time?</p> <p>What if the employee is receiving medical removal benefits, and is injured during normal working hours in a non-job related activity?</p> <p>What if an employee is receiving medical removal benefits, and has an auto accident killing him and others. Is the employer responsible? Is that on the employer's industrial insurance record?</p>	<p>4. Employees that are receiving medical removal benefits are considered to be legally employed and retain all employment rights and benefits. If an employee is removed from work and gets injured in a non-job related activity it would be considered as if the employee was on paid leave.</p>
9.41	<p>It says that in the rule to provide medical removal protection benefits. I have big bold letters that say this is L&amp;I's responsibility. That's workman comp. That's Labor &amp; Industries insurance. That is why we have it. That is what I am paying for. And I should not be burdened with absorbing this cost any more than if a guy suddenly can't hear, or he hurt his back, or he broke his leg, or he sprained an ankle. But in this case, I am now going to take on part of the L&amp;I workman comp responsibility.</p>	<p><b>No change in rule</b></p> <p>Medical Removal Protection Benefits are not workers compensation benefits. The cholinesterase-monitoring rule has no effect on the industrial insurance system. A primary goal of the cholinesterase monitoring rule is to identify employees who have experienced overexposure to cholinesterase-inhibiting pesticides and remove those employees from further preventing illness. If the rule functions as designed compensable claims due to pesticide related illnesses will be avoided.</p> <p>On the other hand it is logical to assume that the rule will increase the number of diagnosed pesticide illness. Currently, without a proper diagnosis, a poisoned worker misses work and is not paid for medical costs or lost wages from undiagnosed pesticide poisoning. After the rule takes effect, many of these pesticide handlers are likely to be 'brought into' the workers compensation system as a result of the ongoing monitoring program. The rule will help to accomplish an important goal of the workers compensation system by compensating workers for occupationally caused illnesses, in accordance with existing legal mandates found in the industrial insurance act.</p>
9.42	Why should farmers be responsible to pay for medical removal when it is	<b>No change in rule</b>

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### Select Comments and Responses Summarized by Category or Subject Matter

Issue Number	Typical Comments or Typical Point(s)	Response
	<p>subsequently determined that the worker was not exposed? Please compensate farmers with safe operations by allowing them to deduct the cost of this program from workers' compensation premiums.</p>	<p>Issues regarding the Industrial Insurance system and workers compensation are outside of the scope of the cholinesterase-monitoring rule. The rule has no effect on the Industrial Insurance system.</p>
9.43	<p>Requiring an employer to provide a job for a worker who has depressed cholinesterase levels for up to three months (307-14830) is not acceptable. This worker may not have been following required safety procedures. One month should be more than adequate.</p>	<p><b>No change in rule</b></p> <p>The length of worker protection benefits is determined based on the known toxicologic and physiologic effects of a toxic substance. The only indication for the estimated length of time for a medical removal period that could be found in field studies is an average of 3.5 weeks (Lessinger &amp; Filmore (1993). A cholinesterase testing program for pesticide applicators. <i>Journal of Occupational Medicine</i>). In this study the results of data on 100 workers who had ongoing cholinesterase monitoring were evaluated. The shortest time an employee was removed from exposure was 1 day. The longest removal period was 119 days. Removing these outliers from the calculation, it is reasonable to expect a 22-day average removal period. Given this information the department feels that 3 months maximum medical removal protection is appropriate.</p> <p>WAC 296-307-10005 states that employers "must ensure that employees are protected from injury or impairment of any bodily function that might occur through absorption, inhalation or physical contact of any substance, vapor, radiation, or physical hazard. Wherever appropriate, you must ensure that employees use protective clothing; respiratory devices; shields; barriers; and adequate protective equipment for eyes, face, head, and extremities." It is the employer's responsibility to take necessary action to ensure the employee's appropriate usage of personal protective equipment.</p>

**WAC 296-307-14835 Maintain medical monitoring records.**

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9.44	<p>This section should require that both doctors and employers maintain the monitoring records. Employer must maintain records to facilitate access by inspectors and workers, <i>i.e.</i>, so they do not have to go off the work site to get them. Doctors should also maintain records as employees may be less intimidated about asking the medical provider to see them. Doctors should also retain the records to provide proper medical supervision and appropriate medical monitoring recommendations.</p>	<p><b>No change in rule</b></p> <p>Occupational safety and health regulation is limited to the employer/employee relationship. The employer is responsible for ensuring that all regulatory requirements are met. The employer is required to ensure that employee medical records are maintained. All personal medical records, whether work or non-work related must be maintained confidentially in accordance with RCW 70.02. In practice this means that the employer's medical provider maintains employee medical records in a confidential manner on behalf of the employer. The employer does not have the ability to access employee medical information without specific written authorization from the employee. (see RCW 70.02 Medical Information)</p> <p><b>No change in rule</b></p> <p>The department feels that this statement adds confusion. All declination statements must be retained, adding the term "where applicable" implies that there are some situations in which it is not necessary to retain declination statements.</p>
9.45	<p>The requirement to retain signed declination statements should be changed to: "Signed declination statements, where applicable."</p>	<p><b>No change in rule</b></p> <p>Cholinesterase test results are being added the Washington State Notifiable Conditions list, WAC 246-100-001. The Department will have access to test data maintained by the Department of Health in an aggregate electronic database. Reports will be generated from the information contained in this database in order to evaluate the efficacy of the cholinesterase-monitoring rule.</p> <p>As already stated, the department is not prepared to initiate a statewide employee and employer identification system due to a variety of resource dependant and legal issues. Tracking of employee test results will be accomplished through the established Cholinesterase Monitoring Data system.</p>
9.46	<p>L&amp;I should create and maintain a centralized database for information that employers, laboratories, and health care providers submit to L&amp;I. We propose the following language to describe this database:</p> <p>The department will</p> <ul style="list-style-type: none"> <li>• Create and maintain an electronic database that contains information that laboratories, employers, and health care providers will submit to the department as required by this rule. Non-confidential information from the database will be accessible through the agency's web site.</li> <li>• Ensure that this database provides a centralized system that facilitates analysis of data on the adequacy and effectiveness of the monitoring program.</li> <li>• Assist and encourage employers and health care providers to submit data in electronic form for automated entry into the database. The department will not reduce the level of required information or alter the timing for data submitted in electronic form.</li> </ul>	

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Issue Number	Typical Comments or Typical Point(s)	Response
	<ul style="list-style-type: none"> <li>Provide reporting protocols that laboratories must use to electronically submit test results to the department.</li> <li>Ensure that reporting forms and protocols for different pieces of information include employee and employer-specific identification numbers so that monitoring results can be linked to handling information and to actions taken in investigations and removals.</li> </ul>	
9.47	The rules should specify that L&I must investigate workplaces at which cholinesterase depressions trigger worker removals and/or workplace investigations by employers.	<p><b>No change in rule</b></p> <p>The department will investigate all cholinesterase depressions to the work removal level pursuant to our responsibilities as stated under RCW 49.17. A detailed enforcement plan is included in the narrative of this Concise Explanatory Statement.</p>
9.48	Last bullet point: "Make sure that medical monitoring records are readily accessible to the employee and his designated representative."	<p>Due to increased national concern over privacy issues, especially in regards to medical issues, the designated representative should be identified, in writing, and provided by the individual whose health information is being sought. (Example, I currently have to sign a Protected Health Information form, provided by my pharmacist that notifies me, who can/many access the prescription data.) Due to potential legal issues, the employer need clear written documentation signed by the employee as to who can receive the information.</p> <p>The department agrees that confidentiality of medical records is a paramount concern to both employees and employers. This item in WAC 296-307-14835 has been amended to read:</p> <ul style="list-style-type: none"> <li><i>Make sure that all records are readily accessible to the employee and his or her designated representative.</i></li> </ul> <p>Also clarification has been provided in WAC 296-307-14815 with a requirement for the employers as follows:</p> <ul style="list-style-type: none"> <li><i>Instruct the physician or other licensed health care professional (LHCP) to NOT reveal in writing or in any other communication with you, personally identifiable medical information, other than laboratory test results, for any employee.</i></li> </ul>
9.49	L&I should amend Section 14835 to require that employers promptly submit test results, medical supervisor recommendations, and handling records to L&I whenever: 1) medical supervisors recommend workplace	Requiring employers to submit test results, medical supervisor recommendations, and handling records is an undue burden. Employers are already required to maintain these records. The department may access these records as necessary

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	improvements, investigations or worker removals, or ii) cholinesterase levels dip to 70% of baseline or less for RBC tests or 60% of baseline or less for plasma tests. The department should establish an electronic reporting system which makes reporting easy and which facilitates use of the data. It should encourage employers to submit handling data via this electronic system even in the absence of significant depressions or supervisor recommendations for action. When corrective actions or removals are necessary, employers should also be required to submit information about these actions to L&I, including, for example: results of investigations, documentation of corrective measures that have been implemented, and details of when workers were removed and when they returned to handling tasks.	through existing means outlined in RCW 49.17.
9.50	<b>WAC 296-307-14840 Provide training.</b>  What is acceptable documentation that the required information and training was provided to employees?	<b>No change in rule</b>  The cholinesterase-monitoring rule does not require documentation of training. Compliance with this section will be determined through employee and employer interviews and review of pesticide handler training course descriptions
9.51	Maintaining medical records I find interesting. I understand by the rules it is seven years. And for the life of me, I do not understand why I, specifically, would keep those records for seven years when I must assume that it is in the best interest of the State of Washington or Labor & Industries to be able to have a track on an individual who may spray formed this year and next year and then move down to John Doe.	<b>No change in rule</b>  All efforts have been made to coordinate the cholinesterase-monitoring rule with existing requirements. Employers currently must retain pesticide application records for seven years. Requiring all pesticide handling records to be retained for seven years will allow employers to streamline their recordkeeping system and avoid the confusion that would be inherent in different record retention requirements.
9.52	<b>WAC 296-307-14845 Implementation plan.</b>  The department must directly pay all medical provider and lab costs.	<b>No change in rule</b>  RCW 49.17 states that “where appropriate, any such rule shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in

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		<p>order to most effectively determine whether the health of such employees is adversely affected by such exposure”</p> <p>The department has received a legislative appropriation of \$378,000 that will be used to mitigate medical monitoring costs during the first year and support surveillance activities.</p>
9.53	<p>The proposed cholinesterase rule should include an enforcement plan. To be effective, the cholinesterase (ChE) rule must be fully complied with, and to ensure that happens the rule must include an adequate enforcement plan. Although the proposed rule includes an “implementation plan” (WAC 296-307-14845), it includes no discussion of how L&amp;I will ensure the rule is enforced and complied with. L&amp;I should remedy this omission by including an enforcement plan in the final rule.</p>	<p><b>No change in rule</b></p> <p>A detailed enforcement plan is included in the narrative of the Concise Explanatory statement.</p>
9.54	<p>We have concerns about how WISHA will structure citations and penalties for violations of this proposed rule. The department has no evidence or proof that lack of cholinesterase monitoring should constitute a serious violation. Therefore, any violations of the cholinesterase-monitoring rules should be regarded as general violations.</p>	<p><b>No change in rule</b></p> <p>Citations will be calculated according to the procedures outlined in WAC 296-800-350, WISHA Appeal, Penalties and other Procedural Rule.</p>
9.55	<p>The rule must be drafted in a way, which ensures collection of all needed data and the ability of L&amp;I, evaluators, and others to access and use that data effectively.</p>	<p><b>No change in rule</b></p> <p>The department will establish independent scientific and stakeholder groups to direct data collection and conduct rule evaluation activities.</p>
9.56	<p>If a worker is trained to wear safety equipment and he refuses to wear the equipment and subsequently becomes exposed, what should be done?</p>	<p><b>No change in rule</b></p> <p>WAC 297-307-13045 Worker Protection Standard requires employers to ensure employees use personal protective equipment as required per the product label. It is the employer’s responsibility to ensure compliance with the rule.</p>
9.57	<p>The agriculture industry by nature tends to have a migrant population. It would be difficult to maintain accurate medical records of employees who are not necessarily employed with the same employer year after year. The financial cost of having to do medical monitoring and record keeping on a</p>	<p><b>No change in rule</b></p> <p>Employers are only required to maintain medical records of employees that are related to their employment time. There is no requirement to maintain an</p>

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9.58	"revolving door" population would cause an undue hardship to agriculture employers. Washington State employment laws are prohibitive of pre-employment screening that might prejudice the employer from hiring an applicant who had previous exposure to organophosphates or carbamates. Medical records are confidential and do not have to be made available to potential employers. Potential employees may deny any history of exposure to these pesticides to prevent from being denied employment.	aggregate medical record that contains medical information from all employers that an individual has worked for. <b>No change in rule</b> Employers may ask medical questions related to job requirements after a bona fide job offer has been made.
9.59	We are concerned about protecting the health of pesticide applicators. The best way to provide that protection in the immediate future is to use properly designed protective equipment and professional pesticide handling procedures, and to provide well-designed, regular training to applicators. In the long run, a medical monitoring program may have a place for some pesticide applicators, but it is important that the state determine at what exposure threshold monitoring actually becomes a benefit to pesticide handlers, and to base the regulation on that data.	<b>No change in rule</b> The cholinesterase-monitoring rule states "the department will adjust the threshold for medical monitoring of employee under this rule on February 1, 2005, if the data collected during 2004 clearly demonstrates that the threshold should be either lower or higher than thirty hours."
9.60	<b>Appendix A</b> The proposed title of the (declination) form is vague and misleading. It should be called "Form for Declining Participation in Cholinesterase Medical Monitoring." This form should be provided in the worker's language. L&I should include a Spanish version in the Appendix. The form should also state: 'I understand that the decision on participating in cholinesterase testing is mine alone, and that my employer may not influence my decision. It is unlawful for an employer to change a worker's employment status based on the worker participating in the testing program.' The form should state that if the worker changes his or her mind, the worker or the worker's representative should contact the medical provider to request testing.	<b>Rule change</b> Appendix A has been removed. The department has decided to include a sample medical consent form as a helpful Tool. The sample consent form has been developed by physician/scientists at the University of Washington and includes the option to participate or decline participation in the cholinesterase-testing program. This sample form will be provided in both English and Spanish. In addition, English and Spanish version audiotapes will be provided to health care providers. The reference to Appendix A in WAC 296-307-14820 has been removed.
10.0	<b>Miscellaneous comments</b>	
10.01	I am an area horticulturist for a number of growers here in the valley who	The department agrees that the timing of the public hearings made it difficult for

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	was not able to testify today due to the timing of the meetings since we are in the middle of harvest. Looking for a way to get public comment, picking in the middle of harvest I thought was a pretty poor choice.	growers to attend. However, if a decision was to be made to adopt or not adopt a rule in time for the 2004 growing season then holding the public hearings in August-September was necessary. All interested parties had the opportunity to submit written comments on the rule proposal or through the oral testimony of designated representatives.
10.02	Representatives of agricultural employers and employees jointly proposed a framework (Agreed Framework) for cholinesterase monitoring rules in the letter to L&I's Director, Paul Trause, and Assistant Director, Michael Silverstein, dated April 18, 2003. It is our understanding that L&I has acknowledged that the Agreed Framework is a constructive basis for adopting a rule acceptable to both employers and employees. The Agreed Framework accepts the necessity of adopting a mandatory cholinesterase-monitoring rule, and proposes that such a rule go into effect on January 15, 2004.	The agreements and proposed frameworks contained in the April 21, 2003 to Paul Trause were duly considered in structuring the final rule. The department recognizes and appreciates the efforts of all parties involved to come to agreement regarding many of the major issues involved in the development of a cholinesterase-monitoring rule

**Appendix B to Concise Explanatory Statement**  
**Response to Comments by the Washington Farm Bureau**  
December 2, 2003

In responding to the Washington Farm Bureau's comments on the rule proposal, submitted by Dan Fazio on September 8, 2003, the department emphasizes the following key points that are discussed in more detail in the following pages:

- The department has considered the entire record and made its decisions based on the best available data reflecting the risk to pesticide handlers in agriculture. The department has carefully analyzed and made appropriate adjustments to pre-1993 data, rather than discarding it entirely as the Farm Bureau suggests.
- The department has concluded that there will be no meaningful number of “false positives” at the medical removal level. The Farm Bureau’s conclusion to the contrary is based on a misunderstanding and misapplication of various pieces of information. To the limited extent such so-called “false positives” may occur, the cost analysis overstates their costs by treating them as full medical removals.
- The department has concluded that the legitimate technical issues reflected by the record can be and have been appropriately addressed by the rule being adopted. To the extent that the Farm Bureau’s comments provide specifics about their technical concerns, those concerns either are not relevant to the approach taken by the department or have been appropriately addressed.
- The department made no final decision to adopt, modify or discard the rule prior to its review of the complete rulemaking record. To the department’s knowledge, no department representative has indicated otherwise. The Farm Bureau’s conclusion to the contrary is based on an apparent misunderstanding of statements outside their appropriate context.
- The department has concluded that cholinesterase monitoring is an appropriate and feasible method to enhance the protection of agricultural pesticide handlers from the significant risk represented by cholinesterase-inhibiting category 1 and 2 pesticides. This conclusion was based on a review of the entire record, and took into account the perspective presented by the Farm Bureau comments.

***Section 1: Discussion of data regarding likely over-exposures and best available evidence.***

L&I has made its decisions based on the best available evidence. The basis for these decisions is discussed in greater detail in the main body of the Concise Explanatory Statement (CES). This document focuses on comments by the Washington Farm Bureau and should not be considered a complete statement of L&I’s position on these issues.

The Farm Bureau states that the “numbers of workers who will be injured or face medical removal due to work related cholinesterase depression is extremely small – from 0- 1%.” It attributes this conclusion to Das, Felsot, Keifer, Smith, PIRT, and workers compensation data.

The Farm Bureau also argues that there “will be a significant number of abnormal cholinesterase tests – in the 3-10% range.” It attributes this conclusion to Lessenger, Das, Keifer, and Smith.

And the Farm Bureau argues that “Prior to the adoption in 1993 of personal protective equipment regulations, changes in pesticide formulations, and the industry practice of limiting pesticides, there were more frequent exposures and would have resulted in more medical removals” a conclusion it attributes to Lessenger.

In order to discuss each of these arguments, the department has reviewed the information upon which the Farm Bureau has apparently relied.

Preliminary Findings by Dr. Das.

The Farm Bureau is incorrect in its suggestion that a preliminary analysis of selected recent California data suggests a removal rate of less than one percent. The Farm Bureau is also incorrect in its suggestion that the same data supports its contention that there will be a meaningful number of “false positives” that should be reflected in the cost analysis.

Dr. Rupali Das, M.D., M.P.H., works for the California Department of Health Services. As noted by the Farm Bureau, Dr. Das provided preliminary information to L&I’s John Furman, PhD. Based on that preliminary data, which she asked not be quoted or used, Dr. Das indicated to Dr. Furman that it appeared that 2 percent of California workers are being medically removed. She also included a number of caveats limiting the data’s usefulness and general applicability.<sup>1</sup>

Unfortunately, it appears that Dr. Das’s readiness to share admittedly preliminary information has generated confusion on the part of the Farm Bureau. Before discussing the data itself, it is appropriate to share the sequence of events related to its discussion with the Farm Bureau.

Dr. Das shared a set of PowerPoint slides regarding her research with L&I.<sup>2</sup> After receiving them, Dr. Furman provided the slides to the Farm Bureau and other stakeholders on an informational basis.

After L&I filed its proposed rule and during the public comment period, Dan Fazio of the Farm Bureau asked L&I’s regulatory economist some questions about Dr. Das’s presentation in a phone conversation. The questions were referred to Dr. Furman,<sup>3</sup> who responded with an e-mail to Mr. Fazio providing a clean copy of the presentation and attempting to answer what he understood to be Mr. Fazio’s questions about the data, based on Dr. Furman’s own review of the presentation. The note makes it clear that Dr. Furman is simply interpreting the data on the slides themselves (and at one point acknowledges that he is not readily able to do so).<sup>4</sup> Dr. Furman also appropriately included Dr. Das’s contact information so that Mr. Fazio could follow up with her directly.

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<sup>1</sup> Michael Wood’s copy of an e-mail from John Furman to several L&I colleagues, dated September 11, 2002, sharing Dr. Das’ e-mail to him of the same date; included in Washington Farm Bureau comments of September 8, 2003 as Attachment 6.

<sup>2</sup> Dr. Rupali Das’s PowerPoint presentation; included in WFB comments of September 8, 2003 as Attachment 9.

<sup>3</sup> E-mail from Reinhold Groepler to John Furman, dated August 22, 2003; included as part of Attachment 7 in WFB September 8, 2003 comments.

<sup>4</sup> E-mail from John Furman to Dan Fazio, dated August 22, 2003; included as part of Attachment 7 in WFB September 8, 2003 comments.

Mr. Fazio responded by asking Dr. Furman in an e-mail if the data meant “bottom line” that the figures demonstrated a depression indicating workplace removal in 463 individuals.<sup>5</sup> Dr. Furman responded “No it does not say that 463 workers had depressions requiring medical removal only that they had depressions” and referred to a previous communication with Dr. Das when she said that the preliminary analysis indicated that 1-2 percent of the cases had depressions to the work removal level.<sup>6</sup> Mr. Fazio then followed up with an e-mail including seven specific questions regarding the data, the study period, the meaning of the slides, etc.<sup>7</sup> Upon reviewing the series of notes on which he had been copied, Senior Program Manager Michael Wood instructed staff (in a note openly shared with Mr. Fazio at the time) to discontinue sending additional notes until further conversation had taken place.<sup>8</sup> Specifically, Mr. Wood was concerned that the status of these e-mail exchanges in relation to the public comment period was not clear and that Dr. Furman was being asked to interpret and supplement a PowerPoint presentation that was as readily available to Mr. Fazio as to Dr. Furman. After discussing these concerns, Dr. Furman agreed that it was more appropriate to ask Dr. Das to speak to her own presentation, and responded to Mr. Fazio to that effect.<sup>9</sup>

In response to Mr. Fazio’s inquiry, Dr. Das (obviously unaware of the L&I concerns about interpreting her data and providing answers to questions during the public comment period) referred him to Dr. Furman to avoid repeating the general information she had already given L&I. She also stated that they were “completing our final data analysis” and that she “would prefer not to commit to detailed responses on our data at this time.”<sup>10</sup> When Mr. Fazio told her of Dr. Furman’s reluctance to provide additional information, Dr. Das did answer the question of how many workers were involved in the survey and “how many work related cholinesterase depression removals” were recorded by indicating “based on data we have so far: 463 cases, 11 removals.”<sup>11</sup>

Commenting on this preliminary data, the Farm Bureau describes her presentation as “ambiguous” and then proceeds to draw inaccurate conclusions from the same “ambiguous” data. Dr. Das’s September 4, 2003 e-mail to Mr. Fazio clearly distinguishes between depressions and depressions requiring medical removal.<sup>12</sup> Dr. Furman’s August 22, 2003, e-mail to Mr. Fazio refers to the distinction between “depressions” and “depressions to the work removal level.”<sup>13</sup> The Farm Bureau’s comments mistakenly conclude that Dr. Das’s data indicate “false positives” that would have required work removal if they had not been investigated. In reality,

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<sup>5</sup> E-mail from Dan Fazio to John Furman, dated August 22, 2003, included as part of Attachment 7 in WFB September 8, 2003 comments.

<sup>6</sup> E-mail from John Furman to Dan Fazio, dated August 22, 2003, included as part of Attachment 7 in WFB September 8, 2003 comments.

<sup>7</sup> E-mail from Dan Fazio to John Furman, dated August 22, 2003, included as part of Attachment 7 in WFB September 8, 2003 comments.

<sup>8</sup> E-mail from Michael Wood to John Furman and Dan Fazio, dated August 22, 2003, included as part of Attachment 7 in WFB September 8, 2003 comments.

<sup>9</sup> E-mail from John Furman to Dan Fazio, dated August 25, 2003, included as part of Attachment 5 in WFB September 8, 2003 comments.

<sup>10</sup> E-mail from Rupali Das to Dan Fazio, dated September 4, 2003, included as part of Attachment 8 in WFB September 8, 2003 comments.

<sup>11</sup> E-mail exchange between Rupali Das and Dan Fazio, dated September 4, 2003, included as part of Attachment 8 in WFB September 8, 2003 comments.

<sup>12</sup> E-mail exchange between Rupali Das and Dan Fazio, dated September 4, 2003, included as part of Attachment 8 in WFB September 8, 2003 comments.

<sup>13</sup> E-mail from John Furman to Dan Fazio, dated August 22, 2003, included as part of Attachment 7 in WFB September 8, 2003 comments.

Dr. Das's data indicates a much larger number of smaller depressions. While these smaller depressions do not rise to the work removal level under either the Washington or California rules, they are nonetheless suggestive of pre-clinical work-related depressions. Dr. Das, in her comments to Carol Dansereau of the Farmworker Pesticide Project, makes it clear that it is the relatively small degree of depression, not the reason for the depression, that prevents more medical removals from occurring.<sup>14</sup>

The data is preliminary and the author cautions against its use. Moreover, the data is voluntary and involves only three labs. In addition, the data is not necessarily limited to pesticide handlers, agricultural workers, or even workers in general. Dr. Das believes that this relatively low level of cholinesterase depression to the medical removal level is the result of the presence of mandatory medical monitoring in California for more than two decades. Clearly, there are a number of reasons why this number should be treated with considerable caution. For this reason, the department is not relying upon this preliminary information to any meaningful degree in its rulemaking.

However, it is worth noting that this preliminary data does *not* suggest a radically different removal rate than that anticipated by the benefit-cost determination and other documents related to the Washington rule. If 463 cases resulted in 11 medical removals, that is a removal rate of just under 2.4 percent (rather than the two percent, or 1 to 2 percent, preliminary number that Dr. Das had previously provided and that Dr. Furman had previously passed on to Mr. Fazio). The department's estimated removal rate in its central analysis of the costs (and benefits) is 3.0 percent, and its low estimate of 1.2 percent is actually half that suggested by Dr. Das's preliminary numbers. For reasons explained in the Benefit-Cost Determination, L&I has determined that the actual removal rate is likely to be lower than that experienced by California at an earlier point in the monitoring program's existence. However, L&I expects the Washington removal rate to be somewhat higher than that experienced in California more than two decades after medical monitoring was first required. Dr. Das's preliminary information does nothing to contradict the department's expectations in that regard.

#### Dr. Felsot's analysis of the likelihood of identifying depressions

The Farm Bureau relies on the analysis by Dr. Allan Felsot of Washington State University as a basis for presuming that cholinesterase monitoring will identify actual depressions at a level between  $\frac{1}{2}$  percent and one percent. This reliance is misplaced and based on a misunderstanding of one of the primary benefits of medical monitoring – to ensure the effective use of personal protective equipment (as well as appropriate work practices and engineering controls).

Dr. Felsot discusses the likelihood of detecting depressions in a six-page attachment to the Farm Bureau comments. He concludes, "Based on EPA's exposure assessments, medical monitoring of cholinesterase enzyme activity is unlikely to detect significant depression."<sup>15</sup> However, the EPA assessments in question presume for their purposes the correct use of personal protective equipment (PPE). As Dr. Felsot notes, "According to EPA's analyses, *use of recommended personal protection equipment (PPE)* would prevent measurable cholinesterase depression. Given the expected low levels of worker exposure *when proper PPE is used*, medical diagnostic

<sup>14</sup> E-mail from Rupali Das to Carol Dansereau, dated October 7, 2003, included as an attachment to Ms. Dansereau's October 3, 2003 comments on behalf of the Farmworker Pesticide Project.

<sup>15</sup> "What is the likelihood of detecting changes..." by Dr. Allan Felsot, included in WFB Comments of September 8, 2003, as Attachment 18, page 6.

laboratories will face great difficulties in determining any changes in cholinesterase activity from pre-work baseline levels.”<sup>16</sup> [emphasis added]

L&I agrees that optimal use of PPE, and engineering and work practice controls, as mandated by the Worker Protection Standard should be sufficient protection to avoid cholinesterase depression in the majority of cases. Unfortunately, optimal consistent use of PPE does not typically occur in normal field operations, and the EPA has identified the failure to use PPE as a major ongoing problem in the industry. It would be irrational to assume that PPE will always or almost always be used correctly, particularly when the EPA’s conclusions concerning misuse of PPE are supported by anecdotal evidence from both supporters and opponents of the Washington rule.

As discussed in more detail in the main body of the CES, the department has concluded that a well-run cholinesterase-monitoring program will be an effective tool for identifying exposures that occur despite the existence of the Worker Protection Standard and will work in tandem with existing PPE, work practice and engineering control requirements to prevent cholinesterase poisoning.

Nothing in Dr. Felsot’s analysis indicates at what level the department can expect to identify actual depressions, perhaps resulting from a failure to enforce the use of appropriate PPE. Based on its analysis of the best available evidence, the department has determined that the most likely medical removal rate is 3.0 percent, although it acknowledges a reasonable possibility that the removal rate could be as low as 1.2 percent or as high as 4.8 percent.

#### 1995 Keifer et al analysis of fieldmate test kit

The Farm Bureau references Dr. Matthew Keifer to support the conclusion that depressions requiring work removal will be in the .5 to 1 percent range. It also refers to Dr. Keifer in support of its claim that there will be a large number of “false positives.” The comments apparently are in reference to a pilot application of field-based cholinesterase monitoring in which Dr. Keifer was a leading participant. However, the first conclusion overstates the meaning of Dr. Keifer’s data, and the second conclusion simply cannot be supported based on a study that did not find any depressions at the work removal level.

The Farm Bureau refers to 80 workers who participated in the study documented by the 1995 report. However, the number of pesticide *handlers* participating in the study was 47. Since L&I’s rule applies to handlers, not to field workers and mechanics, L&I has focused on the results related to those 47 individuals. Dr. Keifer’s study was not designed to sample a cross-section of worker exposures, and it relied upon employers who participated voluntarily with the study. While it is true that the study did not identify depressions to the medical removal level (although it did identify relatively mild depressions), that conclusion cannot be separated from the likelihood that growers volunteering for such a study are more likely to ensure the effective use of PPE and appropriate work practices than might be expected of the average grower.

The study expressed concerns about handling of blood samples and the reliability of the laboratory method in the absence of a quality control mechanism.<sup>17</sup> Consistent with those

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<sup>16</sup> “What is the likelihood of detecting changes...” by Dr. Allan Felsot, Attachment 18 to WFB Comments received September 8, 2003, page 1.

concerns, the rule anticipates clinical blood samples analyzed initially by a single laboratory working under a well-designed and rigorous quality assurance program.

In the absence of other data, this study would by itself not support the expectation that roughly 3 percent of pesticide handlers would experience depression requiring medical removal. However, neither the study nor the author's conclusions provides any basis to discard the other available evidence of such depressions.

1993 Karr et al analysis (published in 1998)<sup>18</sup>

The Farm Bureau's comments cite the 1993 study by Catherine Karr and others (including Dr. Keifer) for the proposition that depressions will be between  $\frac{1}{2}$  percent to 1 percent. In reality, the 1993 Karr study does not support the Farm Bureau's position; rather, it provides further evidence that depressions will occur at a level comparable to that estimated by L&I.

The study was a test of the field test kit. It initially included 95 workers, of whom 59 would be covered by the Washington rule (the Farm Bureau's use of the data appears to include all of the workers, even though field workers are not covered by the rule and one of the conclusions of the study was that depressions were more likely for pesticide handlers).

As noted in the Farm Bureau comments, the test kit was recalled by the manufacturer (and replaced) after the baseline tests were conducted. Although the manufacturer indicated no correction factor was necessary, the study team determined using a control group that it would be appropriate to reduce the baselines by 10.3 percent and 15.9 percent, for RBC and plasma, respectively. If the correction factor had not been used, the baselines would have remained at a higher level, making it more likely that depressions would be identified.

Of the 59 employees meeting the "handler" definition, depressions to at least the work practice investigation level were identified in 6 cases (10.2 percent) and to the medical removal level in two of those cases (3.4 percent). However, the kit appeared to be unreliable for plasma cholinesterase. When the plasma results are excluded, the kit identified depressions to the work practice investigation level in 3 cases (5.1 percent) and to the medical removal level in 1 case (1.7 percent). However, this does not reflect what might have been identified had a more reliable plasma testing method been available, so it cannot be considered a complete description of the cholinesterase depression resulting from pesticide handling. In addition, the conservative decision (reached in spite of the manufacturer's assurances) to include a correction factor following the recall of the initial test kits may have excluded otherwise valid results of depressed cholinesterase.

Again, it is important to note that the work practice investigation/evaluation level does not require evaluation to determine whether the depression is work related, and workers with tests

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<sup>17</sup> Keifer et al, "Final Report: A Pilot Application of Field Kit-Based Cholinesterase Monitoring of Pesticide Handlers in Washington State, May-July 1995", September 1997, included in September 8, 2003 comments by WFB as Attachment 14, page 38.

<sup>18</sup> The same data is reflected by SHARP Report 24-3-1993, referred to by the Farm Bureau as the "SHARP Study" and included in the September 8, 2003 comments by WFB as Attachment 21. The SHARP report focused on the evaluation of the testing method (which is not the testing method required by the rule); the 1998 publication of the study includes more discussion of the underlying data as it relates to farmworker exposure and resulting cholinesterase depression.

showing that level of depression will not be removed under the rule, even though they appear to have experience pre-clinical cholinesterase depression. Depressions requiring such investigation can in no way be considered “false positives.”

The study did identify (and exclude) three “false positives,” all of them involving plasma cholinesterase analysis. One (involving a fieldworker) was identified by comparing the field test results with laboratory blood results that showed no significant depression (in other words, it would not have occurred had a laboratory test been used in the first place). A second (also involving a fieldworker) was the result of an obviously inflated baseline. It is not clear why the test kit identified such a baseline. However, the third (and the only one of the three involving a handler who would be covered by the rule) was medically based and would have been likely to occur regardless of the testing method – it is for this reason that the rule includes medical review of the test results. With such medical analysis, any false positive result would be short-lived (and such medically based false positives are likely to result only in relatively recent changes in medical history, as happened in this case). The Karr et al study provides the only clear evidence in the record of such false positives – and the single case not attributed to a testing method different from that used by the rule would represent a 1.85 percent rate, rather than the 3 to 10 percent rate claimed by the Farm Bureau.

#### Workers Compensation and PIRT Data

For reasons discussed more extensively in the main body of the CES, L&I has determined that workers compensation claims, while suggestive of risk, do not represent a complete portrayal of the degree of health effects being suffered by workers. Depressions such as those identified by a well-designed cholinesterase monitoring program are not likely to result in identified workers compensation claims in the absence of such a program, even though pre-clinical effects and the resulting symptomatic illnesses may be occurring.

Although the Farm Bureau treats the Workers Compensation and PIRT data as two different data sets, they are essentially two presentations of the same basic data. In addition, they are each subject to the same limitations based on the inherent difficulties in identifying and documenting workplace illness, particularly in relation to pesticides.

#### California and Lack of Data.

L&I agrees that it is unfortunate that the nearly 30-year experience with cholinesterase monitoring in California has not produced more usable data for analysis. For this reason, L&I has included “data capture” provisions and methods as part of its own rulemaking.

However, L&I can find no basis in the record for the Washington Farm Bureau’s assertion that the reason for this lack of data is that “ChE monitoring is not considered useful.” Dr. Richard Ames clearly attributes it to a lack of readily available data and a lack of staff time to complete such an analysis.<sup>19</sup> His statement that he hopes to do the analysis himself after his retirement does not lead L&I to believe that Dr. Ames sees no value in either the analysis or the monitoring program itself (Dr. Ames subsequent although as yet unpublished analysis, suggesting a removal

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<sup>19</sup> E-mail from Dr. Richard Ames of California, dated August 6, 2002; included as part of Attachment 4 to Washington Farm Bureau’s September 8, 2003 comments.

rate somewhat higher than that he had previously identified, is itself referenced in one of the attachments to the Farm Bureau comments<sup>20</sup>).

### The TAG Report

The Farm Bureau is highly critical of the 1997 review of the cholinesterase monitoring issue by the Technical Advisory Group (TAG). The Farm Bureau may be correct in its suggestion that the TAG report was a critical element of the *Rios* decision. However, L&I's decision to adopt a rule is based, not on the review of the available information found in the TAG report, but on its own review of the current information in the record. At the same time, several of the Farm Bureau's concerns about the TAG report itself deserve comment.

The Farm Bureau correctly notes that the 10 percent reference in the TAG report's discussion of the Karr et al study is, at best, imprecise. However, as noted above, the appropriate figure *in relation to pesticide handlers* is actually greater than 10 percent (before the plasma results are excluded). The Farm Bureau also emphasizes a distinction between the two different trigger levels (workplace investigation versus medical removal), although it blurs that distinction elsewhere in its comments. The TAG report, in its background section, discusses both sets of triggers.<sup>21</sup> And it correctly refers to "trigger levels" rather than "trigger levels requiring medical removal." Although it may not be as clear as it could be, the Farm Bureau's description of the statements in the TAG report as "false statements" requiring "investigation" overstates the extent of any analytical problems. There is, for example, considerably less support for the Farm Bureau's repeated use of the "3-10%" figure in support of the claim of false positives, since the only study to identify a false positive (see Karr et al, above) did not itself produce a number within the 3 to 10 percent range.

### Lessenger and Fillmore

Using 1989 data regarding relatively high-risk pesticide handlers, a study by Dr. Lessenger and Dr. Fillmore reported a 24 percent removal rate. The Farm Bureau correctly notes that the 24 percent figure is not indicative of likely removal rates in Washington and criticizes L&I for including a reference to the Fillmore and Lessenger study in the SBEIS. The Farm Bureau's comments, however, disregard the fact that the SBEIS does not use the 24 percent figure (L&I concluded, as indicated by Dr. Furman's June 20, 2003, e-mail on the subject, that "based on what Dr. Lessenger is saying we should expect to see much smaller removal rates than California experienced in the late '70's and '80's.").<sup>22</sup> Indeed, the SBEIS (and the Benefit-Cost Determination) use the "much smaller" 3.0 percent removal rate for the central estimate.

Dr. Lessenger does, as the Farm Bureau notes, provide a number of reasons for the decrease in medical removals, some (but not all) of which can be expected to apply even in the first year of the Washington rule. However, L&I was not able to find support in the record for the Farm Bureau's statement that Dr. Lessenger believes "the removal process is somewhat subjective." The word "subjective" does not appear in Dr. Furman's report of his conversation with Dr.

<sup>20</sup> Michael Wood's copy of an e-mail from John Furman to Reinhold Groepler, June 20, 2003, included in September 8, 2003 WFB comments.

<sup>21</sup> "Cholinesterase Monitoring in Washington State: Report from the Technical Advisory Group," August 1995, included as Attachment 16 in September 8, 2003 WFB comments, pp. 4-5.

<sup>22</sup> Michael Wood's copy of an e-mail from John Furman to Reinhold Groepler, June 20, 2003, included in September 8, 2003 WFB comments.

Lessenger, which is the source referenced in the Farm Bureau comments.<sup>23</sup> L&I has no reason to view Dr. Lessenger's description of his clinic as having "a reputation for being aggressive about worker removal" as referring to anything more than his insistence that workers subject to cholinesterase depression to medical removal levels be removed from further exposure as required by the California rule.

In any case, the 24 percent medical removal figure is higher than L&I expects in Washington following adoption of the rule and, for that reason, the Lessenger and Fillmore study are not used as a basis for the medical removal rate in the SBEIS or elsewhere. However, as explained in the SBEIS, the Lessenger and Fillmore study represents the best available evidence regarding the duration of medical removal when it does occur. And nothing in the record suggests that the physiological responses studied by Lessenger and Fillmore would have changed in the intervening years.

1999 Simcox et al study of field workers<sup>24</sup>

The Farm Bureau refers to this study as supporting its argument that the exposures regulated by the rule do not occur. However, the Simcox study is irrelevant to the question of handler exposure since it applied to field workers during tree fruit thinning. Such work is not covered by the cholinesterase-monitoring rule being adopted by L&I.

***Section 2: Discussion of testing reliability.***

The Washington Farm Bureau argues that lab results for ChE testing are currently not reliable, and attributes this claim to Smith, Keifer, and Das.

The Farm Bureau also asked L&I to recalculate costs "with an estimate that 3 to 10% of the cholinesterase results will be abnormal and require further investigations by the medical supervisor (of these, over 90% will turn out to be other than work related exposure)." It is not clear on what the 3 to 10% number is based.

Dr. Steven Smith's testimony regarding reliability of cholinesterase testing.

Dr. Smith's testimony<sup>25</sup> (and a set of e-mailed comments he provided to L&I) is the only material available in the record regarding his analysis – L&I does not have any detailed description of the data, nor were his conclusions published (and subjected to peer review). He references an inexplicable depression in relation to a single firefighter, not to "firefighters" as suggested by the Farm Bureau testimony. He also indicates that he and his colleagues found similar results in "some of our orchard workers." Most significantly, Dr. Smith also reports his findings based on the use of blind and split samples, both useful research techniques. Again, the information provided on this research in the record is quite limited.

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<sup>23</sup> Michael Wood's copy of an e-mail from John Furman to Reinhold Groepler, June 20, 2003, included in September 8, 2003 WFB comments.

<sup>24</sup> "Farmworker Exposure to Organophosphorous Pesticide Residues During Apple Thinning in Central Washington State," Simcox, et al, 1999, American Industrial Hygiene Journal; included in the WFB comments of September 8, 2003 as Attachment 17.

<sup>25</sup> Legislative testimony of Steven R. Smith, M.D., M.P.H, on February 25, 2003; included in the WFB comments of September 8, 2003 as Attachment 11.

However, L&I agrees with Dr. Smith's conclusion that cholinesterase monitoring is useful primarily in the context of a well-designed monitoring program that insists upon rigorous quality control of laboratory analyses. It is important to note that Dr. Smith's misgivings about "problems with Red Blood Cell Acetylcholinesterase Testing" in the private sector do not cause him to question the value of the US Army program, which he indicates in the same testimony "has effectively tested worker RBC-ChE since the 1970s."<sup>26</sup> It is an overstatement to suggest that Dr. Smith has concluded that testing is inherently unreliable. Instead, he has clearly concluded that it can be done reliably with sufficient attention to quality assurance. Dr. Smith describes the US Army program as having achieved "interchangeable" results between every lab in the program – a level of rigor that is not necessary for the rule being adopted by L&I, which will rely on a single laboratory for at least the first two years of the rule's existence, which will approve additional laboratories only in the context of the sort of rigorous quality assurance program Dr. Smith rightly expects, and which will direct providers to use the same laboratory for baselines and follow-ups. The degree to which Dr. Smith would disagree with the approach used in either the proposed and final rule is not clear, since both his testimony and his separate comments submitted to L&I were made in advance of the actual rule proposal.

It is worth noting, of course, that Dr. Smith also "is a proponent for an effective Red Blood Cell Acetylcholinesterase Testing Program for workers routinely handling and spraying organophosphate poisons"<sup>27</sup> and indicates that the lack of such monitoring "is certainly not protective of our OP workers and they deserve more."<sup>28</sup> Although Dr. Smith would prefer a pilot program, his judgment regarding the risk itself is consistent with L&I's own finding that there is a significant health risk associated with the use of covered pesticides, and that a well-run cholinesterase monitoring program that addresses the quality assurance issues identified Dr. Smith is an appropriate and effective response to that risk.

#### Other concerns about reliability

The concerns regarding laboratory testing identified by Dr. Keifer's 1995 research have been addressed in the discussion of that research above. It is not clear to what portion of Dr. Das's preliminary research the Farm Bureau refers unless it is to the misreading of her data in relation to "false positives," which has already been discussed.

Based on its review of the entire record, L&I has concluded that a well-design and effectively run cholinesterase monitoring program can be a useful tool in identifying uncontrolled workplace exposures (or confirming, in certain workplaces, that those exposures are being controlled effectively). While L&I shares the Farm Bureau's concern about the importance of quality assurance, L&I has concluded that those concerns have been addressed in the final rule and the resulting program will be both feasible and effective.

#### Work practice investigation versus investigation of possible medical removal

The Farm Bureau misunderstands the "investigation" requirement of the proposed (and final) rule, which is the subject of the e-mails addressed in the Farm Bureau's comments on the subject. The "work practice investigation" is separate and distinct from the medical removal requirement. When testing reports depressions of greater than 20 percent from the baseline, the

<sup>26</sup> Legislative Testimony of Dr. Steven Smith, page 1.

<sup>27</sup> Legislative Testimony of Dr. Steven Smith, page 1.

<sup>28</sup> Legislative Testimony of Dr. Steven Smith, page 3.

employer is required to evaluate the employee's work practices. This has nothing to do with "false positives."

In June, the economist working on the economic analysis asked "whether" and "if so how" to reflect costs for these work practice investigations (resulting from what he described as "minor" depressions, distinguishing them from depressions that could trigger medical removal). Contrary to the portrayal in the Washington Farm Bureau's comments on the subject the economist did not recommend that these costs be included, but simply asked the question. In response to his question, both Michael Silverstein and Michael Wood responded that the cost should be treated as minimal because employers are already expected as a matter of law to be aware of workplace conditions and to respond to them appropriately.<sup>29</sup>

This was reflected in the SBEIS with the following statement: "While the proposed rule requires work practice investigations for handlers that have certain depressed cholinesterase levels found by periodic monitoring, this would not impose more than minimal costs on businesses.

"Employers are already required to be aware of hazardous conditions in their workplaces, and the monitoring results will actually provide them better information to meet their current obligations to identify and correct hazards. Therefore, the costs of the specific requirement to analyze work practices following an identified depression will be minimal and are not otherwise reflected here." Similar language appeared in the Review Draft of the Benefit-Cost Determination and in the final Benefit-Cost Determination. The only comments received suggesting that L&I's assumption was in error were those from the Farm Bureau, which incorrectly and inappropriately linked the question to the separate question of "false positives" that would require medical removal if not investigated. Because no relevant comments were received regarding the cost of work practice investigations/evaluations, L&I's conclusion that the work practice evaluation requirement does not represent a new compliance cost remains unchanged.

#### "False Positives"

The "false positive" issue is addressed above in relation to the studies on which the Farm Bureau has based its erroneous conclusion that there will be a 3 to 10% rate of false positives requiring investigation in order to avoid inappropriate removal. The studies do not provide evidence for such a conclusion. L&I, after reviewing the entire record, has determined based on the best available evidence that such "false positives" will be minimal, although based on the Karr study and some anecdotal accounts, they will occur infrequently.

#### Dr. Michael Silverstein's Technical Concerns

Dr. Silverstein's 1998 testimony in support of his decision "that we will not at this time initiate rulemaking for mandatory cholinesterase monitoring" for agricultural workers exposed to the covered pesticides (the decision itself, of course, was explicitly reversed by the Supreme Court in the *Rios* decision) does not state that cholinesterase monitoring is not feasible. It did acknowledge a series of "technical issues which would require careful review."<sup>30</sup> Those issues, and the way each is addressed by the rule being adopted, are as follows:

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<sup>29</sup> E-mail exchange dated June 5, 2003; included as Attachment 10 in September 8, 2003 WFB comments.

<sup>30</sup> Testimony of Dr. Michael Silverstein, *Rios et al v. L&I*, May 22, 1998; included as part of WFB September 8, 2003 comments as Attachment 12, p. 19.

- *Lack of laboratory certification.* The rule requires all tests to be conducted by the Public Health Laboratory of the Washington Department of Health, which is acquiring new analytical equipment specifically for that purpose. The use of the Public Health Laboratory will enable careful and rigorous quality assurance measures, which can in turn be used to ensure that any labs approved after the first two years can be evaluated against the standard set by the Public Health Laboratory.
- *Potential problems associated with falsely positive or falsely negative test finding.* For reasons discussed elsewhere, L&I has concluded that the risks of a “false positive” are very low, particularly at the medical removal level. While Dr. Silverstein correctly identified this risk in 1998 as an issue that would need to be evaluated and addressed, L&I has concluded based on the record that the tests are sufficiently reliable at the levels described in the rule to represent an appropriate and technologically feasible response to the risks presented by the covered pesticides.
- *Comparability among the various test methods.* During the first two years of the rule’s existence, a single test method will be used. After that time, even if laboratories using different methods are approved, the rule requires that the same laboratory conduct the baseline and all periodic tests for an individual employee, so method-to-method variability will not be an issue.
- *Test-to-test variability.* Based on its review of the record, L&I has concluded that cholinesterase testing, as part of a well designed and rigorous medical monitoring program, is a reliable method of identifying cholinesterase depressions at the levels addressed by the rule.

### ***Section 3: Discussion of Farm Bureau’s Allegation of Inappropriate Bias***

Although L&I prefers to rely upon the record and the support the record provides for the decision to adopt the rule, two accusations of departmental bias on the part of the Farm Bureau require acknowledgment and response.

#### Application of rule limited to agriculture activity

The rule, as proposed and as adopted, applies only to work under the Agriculture Standard, a set of workplace rules specific to the agriculture industry. Although the question of whether the rule would or should apply more broadly has occasionally been raised, no one has proposed that the rule apply to workers outside the agriculture industry.

Even in raising the issue formally in its testimony on the proposed rule, the Farm Bureau does not suggest a broader rule or provide any information about the extent of exposures outside agriculture. Instead, the Farm Bureau takes the position that, since L&I’s proposal does not apply to all workers in the state, L&I is admitting that there is no value to mandatory cholinesterase monitoring. The Farm Bureau does not provide any evidence to support its conclusion or explain the reason for such a conclusion. In addition, the Farm Bureau accuses L&I of “bias” without explaining how the supposed bias relates to the decision on the rule before it.

At the initial stakeholder meeting (April 30, 2002) on the need to initiate rulemaking, the Farm Bureau representative asked L&I if it intended to limit the rulemaking to agriculture exposures. The response given at the time was that the present rulemaking was being initiated in response to the Supreme Court’s *Rios* decision, which ordered L&I “to initiate rulemaking on a mandatory

cholinesterase monitoring program for *agricultural* pesticide handlers.<sup>31</sup> [emphasis added] L&I indicated at that time that it did not plan to engage in broader rulemaking, but that it would consider doing so if data was presented indicating that such a broader rule was appropriate. L&I remains open to considering a broader rule, but based on the record currently before it, has not reached a conclusion that the rule would be appropriate outside the agricultural context that was the subject of the *Rios* decision itself.<sup>32</sup>

In any case, the suggestion that other workers should also be covered, even if true, does not justify a delay in providing appropriate and feasible protection to agricultural workers from the significant risk L&I has identified based upon the rulemaking record.

**Decision to propose and adopt rules**

The Farm Bureau also suggests that L&I can pursue rulemaking only with a “blank slate.” L&I’s position throughout this rulemaking has been that no final decision would be made on whether to adopt a rule before the rulemaking record was complete. L&I is unaware of any statement by a department representative, including Senior Program Manager Michael Wood, that is inconsistent with that position.<sup>33</sup>

The Farm Bureau takes the position that Mr. Wood, in acknowledging that the *Rios* decision did not order L&I to adopt a rule but created a “strong presumption” that the rule would be adopted, indicated that “the department had already decided to adopt the rule.” This statement suggests a fundamental misunderstanding of the nature of “presumption,” a well-established legal concept. Such a presumption, of course, can be rebutted based on evidence that may be provided.<sup>34</sup> In most L&I rulemaking, the department starts with a presumption that a rule is likely – had it not reached at least that basic conclusion, it would not begin substantive discussions about possible rulemaking. In this case, the department recognized the *Rios* court’s decision as ordering it, at a minimum, to formally propose a rule. Normally, L&I (like other regulatory agencies) proposes rules in a belief that a version of the rule is warranted and may ultimately be adopted. To suggest otherwise begs the question of why any regulatory agency would invest resources in rulemaking without at least some belief that adoption of a rule was “necessary.”

In this case, L&I recognized the expectations created by the *Rios* decision as well as its own expectations that cholinesterase monitoring, if examined closely in a formal rulemaking process, was likely to be both a feasible and appropriate response to the risk of pesticide exposure.

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<sup>31</sup> Rios et al v. L&I et al, Washington Supreme Court decision, page #

<sup>32</sup> The reference in the Farm Bureau comments to data in the record refers to an e-mail from the L&I regulatory economist, in which he was questioning whether non-agriculture exposures (specifically, landscapers) should be included in the economic survey because he was under the mistaken impression that such workers *would* be covered by the rule. See e-mail dated March 27, 2003, from Reinhold Groepler, included in WFB September 8, 2003 comments as Attachment 28. Contrary to the Farm Bureau comment to which the e-mail is attached as a comment, it makes no mention of structural pest applicators and firefighters. While the department is aware of limited information suggesting there *might* be risks in other industries justifying regulation, the record presently before it does not provide sufficient information to justify a broader application of the rule.

<sup>33</sup> The department acknowledges that Mr. Wood said at the initial stakeholder meeting that the *Rios* case created a “strong presumption” that a rule would be adopted; the language appearing in quotes in the Farm Bureau’s comments, however, is not a direct quote; it is clearly implausible to believe that Mr. Wood, a department manager speaking for the department, would refer to the department as “they.”

<sup>34</sup> If it were not possible to overcome presumption, no accused person would ever be convicted of a criminal offense in this country, since all such accused individuals are presumed to be legally innocent until they are proven guilty.

Recognizing and acknowledging such a presumption, however, does not indicate that L&I (or any decision maker) has a closed mind on the subject.

In supporting its contention that Mr. Wood referred to a “strong presumption” the Farm Bureau refers to recollections from meeting attendees and internal L&I e-mails but does not refer to a series of e-mails between Mr. Wood and Mr. Fazio,<sup>35</sup> which not only uses the phrase but puts it in its proper context (and explicitly distinguishes it from a suggestion that the decision was predetermined regardless of the record).

An October 16, 2002, e-mail that Mr. Wood wrote in response to concerns expressed by Mr. Fazio about an article published by the Washington Department of Agriculture includes the following statement:

We have, of course, described the court as creating "a strong presumption" and have noted that if we decide to do something other than adopt a rule, it will need to be based on a record that clearly supports such a decision. But we have never described the court as requiring a rule to be adopted.

In a further response on the same day, Mr. Wood wrote a note that included the following statement:

The court made some findings relative to the record, and I have stated from the beginning that the Rios decision creates a strong presumption in favor of the adoption of a rule. I continue to believe that's an accurate reading of the decision. As Michael keeps reminding the stakeholder group, if there is different evidence out there we need to receive it from you -- I do not believe that Rios allows us to conclude that the existing evidence (i.e., the evidence that we had in 1997) is inadequate to justify a rule, although it certainly allows us to consider additional evidence.

In appropriate context, it is clear that Mr. Wood’s acknowledgment of a “presumption” cannot accurately be read as a suggestion that the decision was already made. In fact, these notes both acknowledge the possibility that a decision would be made, based on the record, not to adopt a rule. The correct meaning of the term “presumption,” and the context in which it was used, must be considered in any thoughtful evaluation of the question of inappropriate bias.

The Farm Bureau’s claim that Mr. Wood’s statements have been denied by the department is simply wrong. In the March 6, 2003 meeting with Dan Fazio, Dr. Michael Silverstein did not state that Mr. Wood never acknowledged such a presumption. Dr. Silverstein may, however, have disagreed with Mr. Fazio’s statement that Mr. Wood had stated that a decision was already made. Dr. Silverstein also reiterated at that meeting, as he had in other contexts, that the department would not be making a final decision on the rule until the record was complete.

In any event, the question before the department in making the decision on the rule is whether the record supports – or even demands – that a cholinesterase-monitoring rule be adopted for agricultural pesticide handlers. For reasons explained throughout the Concise Explanatory Statement, the department has concluded that it does.

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<sup>35</sup> Series of e-mails with subject line “no proposed rule yet” exchanged between Senior Program Manager Michael Wood and the Washington Farm Bureau’s Dan Fazio, beginning October 15, 2002 and ending October 22, 2002. Attachment 1 to this document.

#### ***Section 4: Relationship to Previous L&I Decisions***

The Farm Bureau references L&I's prior decisions for the proposition that, "In 1997 the department reviewed all available literature and determined that there was no need for a rule." This statement is incorrect.

The Farm Bureau's support for this statement is a footnote reference to a 1993 decision by Stephen Cant that there was no need for a rule. In relation to that 1993 conclusion, which was upheld by the Supreme Court in the *Rios* decision, it is worth noting that much of the research reflected in the current record (even that relying upon pre-1993 data) was completed, published, or otherwise made available to the department after Mr. Cant's 1993 conclusion.

In 1997, the department was asked to adopt a mandatory cholinesterase-monitoring rule for pesticide handlers in agriculture. As explained in detail in Dr. Silverstein's testimony, the basis for this decision was not "that there was no need for a rule" but that too many priorities compete for scarce rulemaking resources and the rulemaking was likely to be both complex and controversial.<sup>36</sup> In discussing the 1997 decision not to pursue rulemaking, Dr. Silverstein never rejected the value of a cholinesterase-monitoring rule in its own right, but only in relation to the resources that would be required to promulgate it.<sup>37</sup>

Again, the question before the department in its present rulemaking is whether the record supports adoption of a mandatory cholinesterase-monitoring rule for agricultural pesticide handlers. Based on the best available evidence in its review of the entire record, the department has concluded that it does.

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<sup>36</sup> Testimony of Dr. Michael Silverstein, *Rios et al v. L&I*, May 22, 1998; included as part of WFB September 8, 2003 comments as Attachment 12.

<sup>37</sup> The *Rios* court, of course, specifically rejected this argument, and it has no bearing on the department's evaluation of the record before it in any case.

## **APPENDIX C: ADDITIONAL REQUIREMENTS OF THE ADMINISTRATIVE PROCEDURE ACT AND THE WASHINGTON SAFETY AND HEALTH ACT**

### **Analysis of alternatives to rulemaking (RCW 34.05.328(1b))**

L&I considered three primary non-rulemaking alternatives.

- Continuing voluntary cholinesterase monitoring, including increased technical assistance to employers and increased educational efforts;
- Increased enforcement of existing regulations and clearer enforcement policies;
- Relying upon EPA/WSDA regulation and pesticide registration changes

#### **Continuing voluntary efforts**

The department has had a voluntary cholinesterase monitoring rule since 1993. L&I has staff available to provide information and technical assistance to employers to help control pesticide hazards. During this time period, private companies, consultants, safety and health professionals, labor unions, and others have also encouraged and assisted employers. Despite these efforts, farm worker representatives felt these practices were insufficient and, as a result, filed a petition for rulemaking that requested L&I make cholinesterase monitoring mandatory. L&I's denial of this petition led to the challenge that resulted in the *Rios* decision, discussed above. The Washington Supreme Court agreed that denial of the request for rulemaking was arbitrary and capricious and ordered L&I to initiate this rulemaking on mandatory cholinesterase monitoring. Based on evidence in the record L&I has concluded that continued use of the voluntary cholinesterase monitoring rule is insufficient to address the significant risk to pesticide handlers associated with the use of covered pesticides.

The DOH pesticide program report on agricultural illness to handlers from cholinesterase inhibiting from 1997 through 2001 is summarized in the table below. It is difficult to draw conclusions regarding the effectiveness of voluntary monitoring programs from this and other PIRT data. Also, only a few growers indicated they had tested employees with a voluntary cholinesterase-monitoring program.

**Illness Type\* for Agricultural Mixer/Loader/Applicator/Equipment Maintenance Workers\*\* by Cholinesterase Inhibiting Pesticides 1997 – 2001 \*\*\*<sup>105</sup>**

Pesticide	1997		1998		1999		2000		2001		Totals	
	Sys	Top	Sys	Top								
Azinphos methyl		1	2				1	1			3	2
Chlorpyrifos			1				2				3	
Diazinon	1										1	
Dimethoate									1		1	
Phorate					1						1	
Combinations of AChE inhibitors with other products	6	3	1	5	6	1	7	2	4	4	24	15
Totals	7	4	4	5	7	1	10	3	5	4	33	17

\*Type of illness/injury: Sys = Systemic: Any health effects not limited to the skin and/or eye.

Top = Topical: health effects involving only the eyes and/or skin.

\*\*Limited to cases with illness classified by DOH as definitely, probably or possibly due to pesticide exposure.

\*\*\*State of Washington Department of Health

## Using existing rules

The Washington State Supreme Court determined that relying on existing regulations to address pesticide hazards would be an unacceptable alternative to initiating rule making. Existing rules, such as Pesticides (Worker Protection Standard) (WAC 296-307 part I) and Respiratory Protection (WAC 296-62 part E), do establish an obligation for employers to address recognized hazards that can cause pesticide poisoning. These regulations have been used as the basis for WISHA inspections and consultation visits in the past. However, these regulations do not provide employers, employees or L&I staff with the means to evaluate the effectiveness of control measures and PPE in protecting employees from exposures to organophosphate and N-methyl-carbamate pesticides. While these rules affirmatively require employers to take specified “protective” actions to address hazards, they are insufficient to ensure effective monitoring and elimination of employee exposure.

Because these rules do not provide employers a means to verify effective implementation they have not been acceptable tools for ensuring equal protection for all employees at risk for poisoning from covered pesticides. L&I believes that a cholinesterase-monitoring rule will provide more uniform employee protection and more equitable employer impact.

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<sup>105</sup> Figure 10 from the Draft 2003 Annual Pesticide Incident Reporting and Tracking (PIRT) Review Panel Report.

## Relying on EPA/WSDA regulation

Another alternative to rule making is relying on federal EPA and the Washington State Department of Agriculture to control hazardous employee exposure to organophosphate and N-methyl-carbamate pesticides through the pesticide registration process. This alternative was rejected for three reasons. First, WISHA has the opportunity to fashion a rule that reflects the input of Washington State employers and employees and takes into account specific features of the state's crops, growing seasons, pesticide usage, and industry demographics. Second, waiting for EPA/WSDA is unpredictable. EPA is currently involved in an assessment of the WPS and has invested several years in reregistering pesticides. The reregistration effort has produced significant changes aimed at reducing the risk to pesticide handlers; however, some changes are being phased in over several years and EPA has acknowledged the remaining risk to pesticide handlers is significant.<sup>106, 107, 108</sup> Waiting involves a significant risk that additional Washington workers will suffer pesticide poisoning that could be prevented by this rule. Third, WISHA has responsibility for worker safety and health and cannot defer that responsibility to a third party, even a federal or state agency. Furthermore, EPA acknowledges that compliance is a continuing problem and, even in the event of full compliance with their regulations, pesticide handlers will be exposed to an unacceptable level of risk from organophosphate and N-methyl-carbamate pesticides. WISHA must perform an assessment of the need for a regulation that includes evaluating the input and actions of other regulatory agencies.

## Determination that the final rule is the least burdensome alternative for those required to comply that will achieve the general goals and specific statutory objectives (RCW 34.05.328(1d))

L&I considered the following non-rulemaking alternatives to the final rule:

- Continuing voluntary cholinesterase monitoring, including increased technical assistance to employers and increased educational efforts;
- Increased enforcement of existing regulations and with clearer enforcement policies;
- Relying upon EPA/WSDA regulation and pesticide registration changes.

As described above, the non-rulemaking alternatives were rejected because L&I concluded they would not achieve the general goals and specific objectives of the Washington Industrial and Safety and Health Act. It is not necessary, therefore, to determine whether they would be less burdensome ways to achieve the general goals and objectives.

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<sup>106</sup> Revised Occupational Handler Exposure Assessment and Recommendations for the Registration Eligibility Decision Document for Azinphos Methyl, July 10, 2001

<sup>107</sup> Agricultural and Occupational Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Chlorpyrifos, October 6, 1999

<sup>108</sup> Memorandum of Agreement between the Environmental Protection Agency and the Registrants of Pesticide Products Containing Azinphos Methyl, May 23, 2002

L&I considered the following rulemaking alternatives in developing the final rule:

- A rule with a single threshold of 30 hours exposure
- A rule requiring baseline testing and additional testing triggered by an exposure incident
- A rule also covering non-agricultural pesticide handlers
- Excluding medical removal protection from the rule
- A rule exempting small businesses
- A rule limited to commercial applicators

These rulemaking alternatives were rejected because L&I concluded they would be significantly less effective than the final rule or unduly burdensome. A rule with a single threshold of 30 hours would be more burdensome than the phased approach being adopted and would limit the data collected. A rule triggered by an exposure incident is reactive and not protective of employees. Non-agricultural pesticide handlers were excluded due to a lack of available evidence that indicated an equal or greater exposure risk to industries other than agriculture and also to limit the economic burden of the rule during initial implementation to the workers with the highest risk from exposures. Excluding medical removal protection from the rule would provide a strong incentive for farm workers **not** to participate in the testing program. Exempting small business or limiting the rule to commercial applicators would exclude segments of the work force often identified as at high risk.

Based on these considerations L&I concluded that the rule is reasonable and responds to concerns identified in the public process. L&I also concluded that the rule is the least burdensome alternative that will meet the statutory mandate to assure that no employee will suffer material impairment of health or functional capacity for the period of their working life. The rule is economically and technologically feasible. The department believes that the benefits of the rule will better outweigh costs than other alternatives.

### **Consequences of not adopting the rule (RCW 34.05.328(1b))**

If a rule is not adopted as part of a comprehensive strategy to address the risk of handling organophosphate and N-methyl-carbamate pesticides, the effectiveness of the strategy cannot be determined. The established underreporting of occupational illness by the worker population subject to this rule is a strong incentive for this rule. Waiting for employees to have symptoms of poisoning severe enough to seek medical attention is not an acceptable safety and health option under the WISHAct. Furthermore, while the Washington Supreme Court did not specifically order L&I to adopt a rule, the Court did direct L&I to initiate rulemaking. The additional information obtained by L&I during this rulemaking reveals the necessity of this rule.

### **Analysis of pilot rulemaking and negotiated rulemaking (RCW 34.05.310)**

The Washington Administrative Procedure Act encourages regulatory agencies to “develop and use new procedures for reaching agreement among interested parties before publication of notice and the adoption hearing on a proposed rule.” (RCW

34.05.310) More specifically, “An agency must make a determination whether negotiated rule making, pilot rule making, or another process for generating participation from interested parties prior to development of the rule is appropriate.”

L&I used a highly open and inclusive process for generating participation that included public rule development meetings and an advisory committee. Before proceeding to public hearings the department concluded that these rule development conferences and advisory committees had effectively and appropriately provided a much higher than usual degree of public involvement. Although it became clear that consensus among the multiple interested parties was not achievable, the process did successfully identify many shared ideas about possible regulatory measures that would make effective public policy. The department concluded that this represented the maximum amount of pre-proposal agreement possible and the department relied heavily upon these ideas in developing its proposal.

Negotiated rulemaking was considered and rejected for two reasons. First, negotiated rulemaking is discretionary and the process of public rule development meetings and advisory committees was an appropriate and effective alternative. Second, negotiated rulemaking is best suited to public policy issues involving a limited, easily identifiable group of affected parties who are reasonably likely to achieve consensus. The Negotiated Rulemaking Sourcebook, Administrative Conference of the United States<sup>109</sup> describes two key prerequisites for successful negotiated rulemaking: a limited number of identifiable interests affected by the rule and a reasonable likelihood that consensus can be reached.<sup>110</sup> The department concluded that the issue of cholinesterase monitoring affected parties with too widely divergent views to suggest a negotiated rulemaking would be likely to succeed.

Pilot rulemaking was considered and rejected for four reasons. First, pilot rulemaking is discretionary and the process of public rule development meetings and advisory committees was an appropriate and effective alternative. Second, pilot rulemaking is best suited to situations where an agency intends to issue a highly specific, inflexible and experimental regulation and feasibility of compliance is highly uncertain. In this case, the department decided to move ahead with a rule with demonstrated feasibility, based on sound scientific principles and data. L&I concluded that a rule designed in this manner would not benefit from pilot testing. Third, the department decided to incorporate a two-year phase-in period to allow data collection and analysis. Fourth, the rule incorporates an implementation plan including a scientific team to oversee collection and analysis of data.

### **Determination that the rule does not require actions that violate requirements of other federal or state laws (RCW 34.05.328(1e))**

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<sup>109</sup> 37 GPO 1990

<sup>110</sup> The federal Negotiated Rulemaking Act (5 USC 561 et seq) requires regulatory agency heads to consider whether “there are a limited number of identifiable interest that will be significantly affected by the rule... there is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time.”

The department has concluded that this rule does not require employers to violate any federal or state law.

**Determination that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law (RCW 34.05.328(1f))**

The WISHAct and rules adopted under it apply to local and state government employers, as well as to private employers (RCW 49.17.020(3)). The rule makes no distinction between public or private employers and the requirements are based on the presence of identified risk factors without regard to the public or private nature of the employer. In the infrequent event that a public employer is engaged in agricultural pesticide handling, the employer will be covered by the rule.

**Determination whether the rule differs from any federal regulation or statute applicable to the same activity or subject matter (RCW 34.05.328(1g))**

The federal Environmental Protection Agency (EPA) and the Washington State Department of Agriculture (WSDA) regulate pesticides, and the Department of Health (DOH) investigates pesticide exposure incidents. L&I coordinates rules related to pesticide work practices with WSDA. The regulations of EPA and WSDA do not address the issue of cholinesterase monitoring for pesticide handlers. WSDA and DOH have been actively involved in the rule development process and are working with L&I on grower outreach, recordkeeping, and other implementation activities.

**Rule implementation plan (RCW 34.05.328.3)**

**How will L&I implement and enforce the cholinesterase-monitoring rule, including a description of resources?**

This rule has a phase-in of the medical monitoring threshold, which will substantially reduce the first-year costs of the rule.

The rule includes the following implementation plan that identifies resources the department will make available.

The department will implement and complete an evaluation of this rule by doing the following:

- Organize a scientific team to oversee collection and analysis of data collected during 2004 and 2005. L&I will select representatives of the University of Washington, Washington State University, as well as other interested members of the academic and scientific communities, to participate on the team. The team will provide an initial analysis of testing data and any appropriate recommendations directly to L&I and to the cholinesterase monitoring advisory committee by November 1, 2004, and a further analysis and any appropriate recommendations by November 1, 2005. A final report and recommendations will be completed by September 30, 2006.

- Establish a cholinesterase stakeholder advisory committee to evaluate issues related to rule implementation and provider recommendations to the department regarding implementation of the rule and any possible modifications to it. L&I will invite representatives of growers, labor and other affected state agencies to participate on the advisory committee. The committee will have an opportunity to comment on the analysis completed by the scientific team and to make any appropriate recommendations before December 1, 2004, and again before December 1, 2005. In addition, the committee will review the scientific committee's final report and recommendations and provide advice to L&I prior to December 1, 2006.
- Review reports from the scientific team and stakeholder advisory committee, and other relevant information and make modifications to the rule as appropriate.
- Make efforts to defray the costs of medical testing during 2004.
- Prepare and distribute provider guidelines.
- Develop and make available a model employee training program.
- Publish a list of trained providers and certified laboratories on the Internet.
  - Coordinate recordkeeping requirements with the department of agriculture.

**How will L&I inform and educate persons affected by the cholinesterase-monitoring rule?**

L&I will provide educational resources, including model employee training and related written materials, to reduce the administrative burden of the rule on small employers.

L&I will work with the Washington Department of Health (DOH), the University of Washington (UW) and others to identify medical providers interested in providing medical monitoring activities. L&I will provide training to such providers and make their names available to growers, enabling growers to select from among such providers with a minimum of effort and to be assured that the providers are aware of the requirements of the rule and their responsibilities under it.

**How will L&I promote and assist compliance with the cholinesterase-monitoring rule?**

L&I inspectors and consultants will receive formal training on the rule in January 2004. The rule will be enforced in accordance with existing guidance related to inspections and consultations under WISHA.

L&I will work with the Washington State Department of Agriculture (WSDA) to develop recordkeeping materials that can be used for both the documentation requirements of this rule and for existing Worker Protection Standard recordkeeping requirements.

An evaluation form will also be developed that growers can use to conduct and document evaluations of their Worker Protection Program.

WSDA has posted a list of all covered pesticides on their web site and will update this list whenever necessary.

Employer workshops on the rule are scheduled throughout the state during the months of December 2003 and January 2004. Currently there are six locations scheduled Bellingham, Mt. Vernon, Yakima, Moses Lake, Okanogan, and Kennewick. The workshops will be 2 hours in length and provide an in depth description of the rule, resource materials, and an opportunity to have all questions answered.

We have drafted a workshop (Spanish and English versions) for workers who handle ChE-inhibiting pesticides. As soon as a rule is adopted, we plan to ask advocates to review and comment on this workshop as well as other outreach materials we plan to produce. We also plan to ask advocate groups to consider sponsoring, scheduling, and marketing these workshops with our assistance. We plan to deliver worker workshops in January, February and March.

We have contacted UC Davis asking for permission to modify their "Jorge's New Job" video for use in Washington. We plan to produce and distribute a Spanish-English WISHA version of this video to workers, advocate groups, growers, and to appropriate L&I staff and service locations. We also plan to use the "Jorge's New Job" video in our workshops, and to provide copies of the video to the public through our video library. We also plan to provide additional copies of the video on request to advocate groups, L&I service locations, clinics that monitor ChE levels, and to employers of affected workers. The video will be accompanied by a WISHA cover letter explaining that Washington's ChE monitoring will be similar to that depicted in the California video.

L&I will provide communications and outreach to the groups affected by the ChE rule. Currently these plans include distribution of a fact sheet, a press release, radio advertisements and public service announcements, a radio talk-show program, and possibly advertisements and rule information in Spanish-language newspapers. These communications will address the rule, the workshops, and other resources available to affected parties such as consultations, our website, and a toll-free phone number. These communications, the rule, and our outreach materials will be posted on the WISHA website. Many of these outreach communications and materials will be available in Spanish.

Staff from the University of Washington Department of Environmental and Occupational Health Science and the Pacific Northwest Agriculture Safety and Health Center (PNASH) have been working with L&I to develop the following:

- Medical provider workshops on cholinesterase monitoring.
- A Physicians manual on cholinesterase monitoring for Washington (similar to the California Guidelines for Physicians who Supervise Workers Exposed to Cholinesterase-Inhibiting Pesticides).
- An informed consent document (in English and Spanish).

Initial medical provider workshops are scheduled in December in the most highly affected geographic areas of the state. Workshops are currently scheduled for Mt.

Vernon, Yakima, Wenatchee, and Walla Walla. All providers and organizations participating in a workshop will be listed on L&I's cholinesterase monitoring web page. We are also working with the University of Washington School of medicine to provide 24-hour access to a consulting physician.

Although we currently anticipate implementing all these plans, the final mix of training and outreach products and services delivered will be determined by the director, the WISHA management team, and stakeholder needs. Among other stakeholder discussions, L&I will be holding a stakeholder meeting as required by WISHA when a significant legislative rule is adopted and implemented.

**How will L&I evaluate whether the cholinesterase-monitoring rule achieves the purpose for which it was adopted, including use of interim milestones and objectively measurable outcomes?**

L&I will work with employer representatives (including representatives of small businesses) and others to analyze the results of the rule during the first year and to consider modifications of the rule as appropriate. A scientific team consisting of representatives from the University of Washington, Washington State University as well as other interested members of the academic and scientific communities will be assembled. This team will oversee collection and analysis of the data collected during 2004 and 2005. The team will provide reports to L&I regarding rule and system efficacy, and make recommendations for rule modification if necessary. All reports from the scientific team will be made public and shared with stakeholder groups.

In addition to the scientific team, L&I will establish a cholinesterase stakeholder advisory committee. This committee will be made up of representatives of growers, labor and other affected state agencies. The committee will have the opportunity to comment on the analysis and recommendations received from the scientific team and provide advice to L&I.

L&I is working with DOH to establish a cholinesterase monitoring data system (CMDS) for the collection and analysis of test results. This system will be used to notify L&I of worker cholinesterase depressions and to provide data to the scientific team.

**Coordination with OSHA (RCW 34.05.328 (1h))**

Before adopting this rule the Department must coordinate the rule, to the maximum extent practicable, with other federal, state and local laws applicable to the same activity or subject matter.

The federal Worker Protection Standard (WPS) enforced by the Environmental Protection Agency addresses pesticide exposures, although not medical monitoring. L&I and the WSDA have identical rules that implement the requirements of the WPS. The rule being adopted complements the existing state and federal WPS requirements.

An arguably applicable law is the Occupational Safety and Health Act. This act defines the relationship between federal and state occupational safety and health agencies, including the relationship between federal and state rule making. The OSHAct requires approved state plan standards to be as-effective-as Federal standards adopted under the OSHAct in requiring employers to provide both employment and places of employment that are safe and healthful. The OSHAct also states that any approved state plan agency may assert jurisdiction over a safety and health issue with respect to which no standard is in effect under OSHAct section 6. At this time the hazards covered by this rule have not been addressed in standards promulgated under the OSHAct. Therefore there are not limitations or restrictions placed on the Department by the Federal government with respect to adoption of the proposed state standards.

L&I's occupational safety and health program functions under the jurisdiction and oversight of federal OSHA. As part of this relationship L&I meets regularly with regional and national OSHA representatives and provides regular written reports to OSHA on its activities and plans.

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